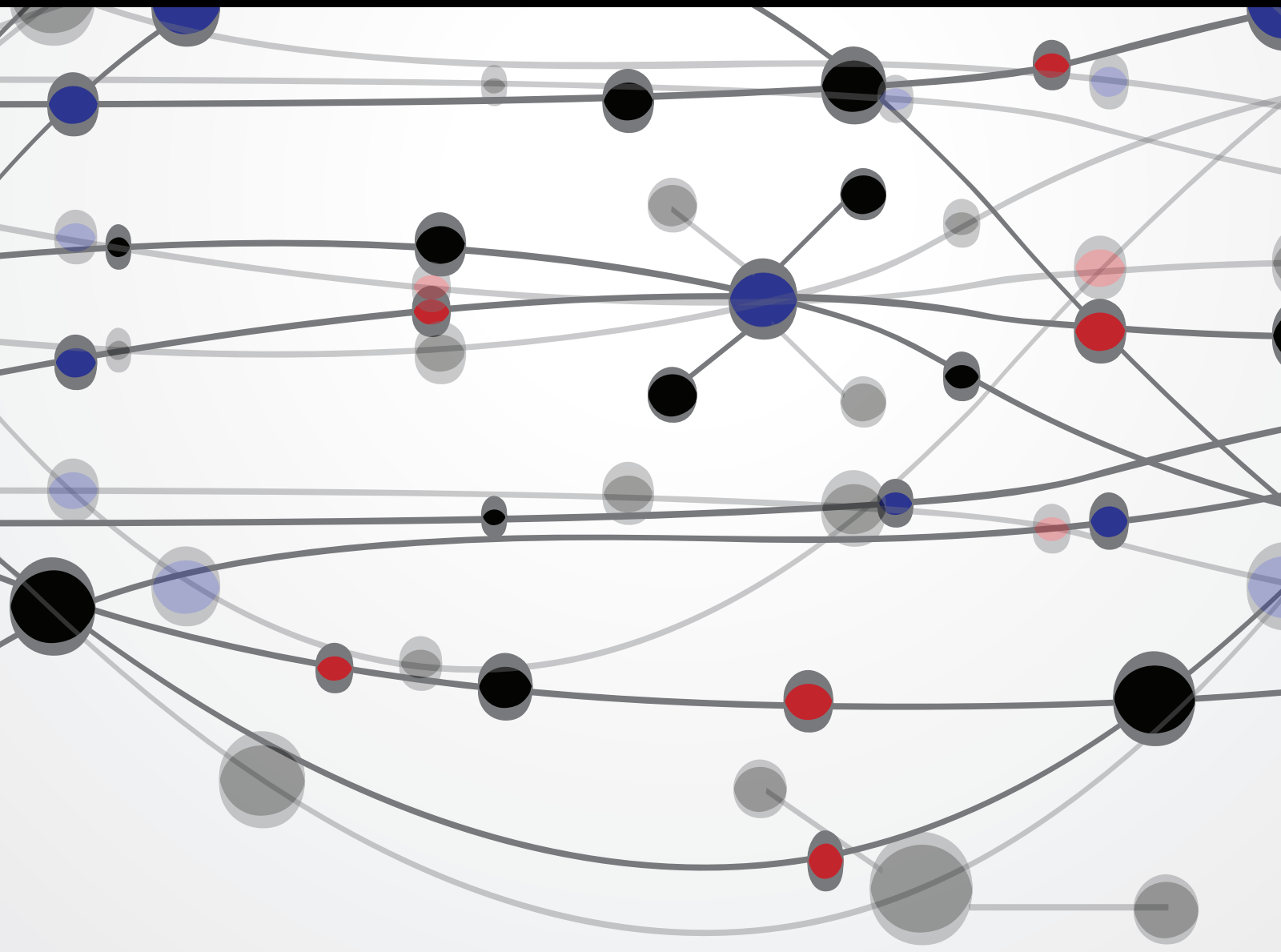
The Scientific World Journal

Advances in Perioperative Management

Guest Editors: Alaa Abd-Elsayed, Elizabeth Frost, and Ehab Farag



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Editorial

Advances in Perioperative Management

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There has been great progress in perioperative management modalities and technologies aimed at improving patient care and safety. This issue includes very important articles in this field. An article by R. Gharabawy et al. discusses the efficacy of ambulatory nerve catheters. The study was done on a large number of patients and showed the safety and feasibility of placing catheters on an outpatient basis. The use of ambulatory nerve catheters aims at reducing admission costs and improving pain control and thus patient satisfaction. Another paper by L.-E. Kang et al. discusses the outcomes related to the use of different cuff pressures of supraglottic airways during abdominal laparoscopic surgeries. This article confirms the safety of using the laryngeal mask airway (LMA) in these surgeries. An article by I. Son et al. presents a double blind randomized controlled trial of the effect of sufentanil administration on remifentanil-based anesthesia during laparoscopic gynecologic surgery. In the article by T. Gaszynska et al. the efficacy of endotracheal intubation using Levitan FPS optical stylet versus LaryFlex video laryngoscope in morbidly obese patients is compared. There have been a lot of advances in airway management in anesthesia, which is not surprising, as intubation/airway management can be life-threatening. It is very important to have multiple modalities available to avoid complications during intubation. Another article by E. Gaszynska et al. reviews a very important topic: satisfaction among anesthesiologists, a critical factor in ensuring better patient outcome. Aside from technology and equipment, we must pay attention to the human element. The article by N. Mehta et al., "*A review of intraoperative goal-directed therapy using arterial waveform analysis for assessment of cardiac output*," considers also noninvasive monitoring. Such technology is rapidly becoming the standard of care for fluid replacement. The article by S.-H. Kim et al. is a double blind randomized controlled trial that shows that total intravenous anesthesia with high-dose remifentanil does not aggravate postoperative nausea and vomiting and pain, when compared with low doses.

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Research Article

Life Satisfaction and Work-Related Satisfaction among Anesthesiologists in Poland

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The aim of the study was to assess the level of life and job satisfaction of Polish anesthesiologists and to explore the impact of extrinsic-hygiene and intrinsic-motivating determinants. *Materials and Methods.* A cross-sectional questionnaire study was conducted among consultant anesthesiologists in Lodz region. The questionnaire concerned patient care, burden, income, personal rewards, professional relations, job satisfaction in general, and life satisfaction. Respondents were asked to rate their level of satisfaction for each item on a seven-point Likert scale (1: extremely dissatisfied; 7: extremely satisfied). *Results.* 86.03% of anesthesiologists were satisfied with their economic status, 77.94% found their health status satisfactory, and 52.21% viewed their personal future optimistically. In general, 71.32% of anesthesiologists were satisfied with their current job situation. Among the less satisfying job aspects were work-related stress (2.49; SD = 1.23), administrative burden (2.85; SD = 1.47), workload (3.63; SD = 1.56), and leisure time (3.09; SD = 1.44). *Conclusions.* Considerable work-related stress leads to job dissatisfaction among anesthesiologists. There is an association between job satisfaction and health status, social life, and economic status. Working for long hours by anesthesiologists results in a high risk of burnout.

1. Background

Job satisfaction is defined as positive feelings of individuals towards their job. According to the Two-Factor Theory of job satisfaction laid out by Herzberg and colleagues, the factors influencing satisfaction levels can be divided into intrinsic-motivating factors (recognition, work tasks, and responsibility) and extrinsic-hygiene factors (job security, working conditions, and salary) [1]. The presence of intrinsic motivators increases satisfaction levels, whereas the lack of extrinsic-hygiene factors may cause dissatisfaction. These factors acting on one another have been shown to be an important modifier of the quality of medical care. Highly satisfied workers care about the quality of their work, are more productive, and feel responsible for the working environment. Staff satisfaction should be a strategic aim of any healthcare system as it facilitates its organization and contributes to cost reduction. Different studies reveal that doctors, anesthesiologists in particular, suffer from occupational stress and burnout [2].

Over the last years working conditions of anesthesiologists in Poland have changed considerably and new forms of employment have emerged. Due to limited healthcare funding, hospitals have faced meticulous financial scrutiny and pressure to generate profits. This entailed a necessity to reduce the costs associated with the services provided (using cheapest treatment options that are not equally effective as other available ones) along with the need to improve workforce productivity. Administrative workload has increased as well. The media-created image of doctors was instrumental in the deterioration of social recognition and respect for medical profession. Doctors have to deal with the threat of

malpractice litigation more than ever. On the other hand, maximum working hours have been reduced and, as a result of the continuous educational obligation, employers are now required to grant paid time-off to employees for further education and professional skills development. At a time of healthcare reorganization in Poland all of the mentioned factors may influence job satisfaction. Research on job satisfaction of anaesthesia providers was carried out in many countries. In Poland still little is known about the work-related well-being of anesthesiologists and the factors that could improve their situation.

The aim of this study was to assess the level of life and job satisfaction of Polish senior specialist anesthesiologists and to explore the impact of extrinsic-hygiene and intrinsic-motivating determinants. A potential modification of these factors may lead to the improvement of anaesthesiologists' performance in the working environment.

2. Materials and Methods

The study was approved by the Medical University of Lodz Research Ethics Board (number RNN/134/13/KB Lodz, Poland). In January 2013 postal survey with a covering letter was sent to all senior specialist anesthesiologists working within Lodzkie Voivodeship. The participants' names came from the register of Voivodeship Consultant updated in the year 2012, which covers all anesthesiologists employed in the Voivodeship. A cross-sectional questionnaire study was conducted among 177 senior specialist anesthesiologists from 14 hospitals in the general area of Lodz. Participants were asked to complete a questionnaire, which was a modified version of the questionnaire introduced by Bovier et al. and was returned in a prepaid envelope by mail. It included questions about each single intrinsic and extrinsic item of job satisfaction: patient care, burden, income, personal rewards, professional relations, and job satisfaction in general [3, 4]. Other variables that are known to influence job satisfaction level were also taken into account: sociodemographic data—age, gender, marital status, years since graduation, mean number of working hours a week, type of employment, and number of employers (number of employment places)—and life satisfaction—standard of living, health status, predictions for the future, and social and family life. Respondents were asked to rate their level of satisfaction with each item on a seven-point Likert scale (1: extremely dissatisfied; 7: extremely satisfied).

2.1. Statistical Analysis. Data were summarized using means and standard deviations and were presented as frequency counts and percentages. Pearson's r correlation coefficients were computed between separate aspects of life and job satisfaction in general. Gender differences in job satisfaction and differences between burnout and satisfied groups were compared using the nonparametric, Mann-Whitney U test. An explanatory factor analysis, principal component analysis with varimax rotation, was conducted in order to define meaningful constituents (dimensions) in terms of work satisfaction among anesthesiologists. Hence, a five-dimensional model was used: patient care (autonomy in treating patients; quality of care one can provide), burden (workload; time available for family, friends, or leisure; work-related stress; administrative burden), income-prestige (current income; social status and respect), personal rewards (intellectual stimulation; opportunity for continuing medical education; enjoyment of work), and professional relations (with peers, nurses, and other staff). Internal consistency (Cronbach's α) of the analyzed subscales is as follows: patient care: $\alpha = 0.78$, burden: $\alpha = 0.70$, income-prestige: $\alpha = 0.55$, personal rewards: $\alpha = 0.81$, and professional relations: $\alpha = 0.71$.

3. Results

The response rate was 76.84% (136/177); 47.79% (65) were men. Average age of the participants was 48.74 years (SD = 9.96; quartiles: 41, 49, and 56.50). Private hospitals were not main employers for any of the respondents. Half of the anesthesiologists were employed in one hospital, 27.94% were employed in 2, and 22.06% were employed in 3 or more. Most anesthesiologists worked under a fixed-term or permanent employment contract and reconciled this with self-employment, that is, contract for services. On average 22.93 years (SD = 10.34; quartiles: 15, 23.5, and 31 respondents graduated from medical school ago) passed since the respondents graduated from medical school.

3.1. Life Satisfaction. Most participants were content (extremely satisfied, satisfied, or rather satisfied) with different aspects of their life: economic status, health status, outlooks for the future, and social and family life—86.03%, 77.94%, 52.21%, 55.15%, and 74.99%, respectively.

3.1.1. Job Satisfaction in General. In general, 71.32% of anesthesiologists were satisfied with their current job situation; most, however, (62.65%) used the term "rather satisfied." Respondents declaring general satisfaction with their job were significantly more content with its different aspects, patient care ($P < 0.001$), income-prestige ($P < 0.001$), personal rewards ($P < 0.001$), burden ($P = 0.009$), professional relations ($P = 0.024$), and life in general, than the dissatisfied ones (Table 1). Family life was the only aspect that these differences did not apply to. The satisfied participants rated their health and economic status significantly higher ($P < 0.001$). They also viewed their future more optimistically ($P < 0.001$) and were more satisfied with their social ($P = 0.036$) and family life ($P = 0.007$).

Table 2 presents statistics describing satisfaction with 13 different job aspects and current job situation. Anesthesiologists' contentment with different job aspects was diverse. Best results were obtained for professional relations with nurses and other staff (5.40; SD = 0.98) and relations with other doctors (5.10; SD = 1.23) as well as enjoyment of work (5.21; SD = 1.14). Among the less satisfying job aspects were factors connected with work-related stress (2.49; SD = 1.23), administrative burden (2.85; SD = 1.47), workload (3.63; SD = 1.56), and leisure time (3.09; SD = 1.44).

Table 1: Computed statistical parameters (mean, SD, and quartiles) for each averaged scoring referring to patient care, burden, income-prestige, personal rewards, and professional relations and different aspects of life among surveyed anesthesiologists being generally satisfied versus dissatisfied[a, b, c].

Investigated "dimensions" of work satisfaction or aspect of life	Job satisfaction in general—declared general satisfaction of work			Job satisfaction in general—declared general dissatisfaction of work[b]			P value[c]
	Mean	SD	Quartiles	Mean	SD	Quartiles	
Patient care	4.78	1.10	4; 5; 5.5	3.69	1.27	2.5; 4; 5	$P < 0.001$
Burden	3.17	1.05	2.25; 3; 4	2.63	0.92	2; 2.5; 3.25	$P = 0.009$
Income-prestige	4.56	0.94	4; 4.5; 5.5	3.69	1.12	3; 3.5; 4.5	$P < 0.001$
Personal rewards	4.83	0.98	4.33; 5; 5.67	3.97	1.19	3; 4; 5	$P < 0.001$
Professional relations	5.40	0.82	5; 5.5; 6	4.86	1.21	4; 5; 6	$P = 0.024$
Material status	5.48	0.86	5; 6; 6	4.79	1.22	4; 5; 6	$P < 0.001$
Health status	5.41	0.94	5; 5; 6	4.49	1.30	4; 5; 5	$P < 0.001$
Predicted future	4.77	1.04	4; 5; 6	4.00	1.08	4; 4; 5	$P < 0.001$
Social life	4.60	1.46	4; 5; 6	3.87	1.94	2; 4; 5	$P = 0.036$
Family life	5.34	1.40	5; 6; 6	5.00	1.59	4; 5; 6	(NS[d])

[a]1: extremely dissatisfied; 2: dissatisfied; 3: rather dissatisfied; 4: neither dissatisfied nor satisfied; 5: rather satisfied; 6: satisfied; 7: extremely satisfied.
[b]"Satisfied anesthesiologists" indicated the score ranging from 5 to 7; "dissatisfied anesthesiologists" chose the score ranging from 1 to 4. The Mann-Whitney U test was carried out.

3.2. Patient Care. 61.8% of the examined anesthesiologists were satisfied with their autonomy in treating patients. 64.6% were satisfied with the quality of care they can provide. A significant relation was observed between the autonomy in patient treatment and satisfaction with the quality of provided care.

3.3. Burden. The lowest satisfaction scores were found for burden. Only 36% were satisfied with their workload while 54.41% were dissatisfied. 72.06% found the time they can devote to their friends and family or leisure activities insufficient. 77.32% were dissatisfied with work-related stress (assessed as too high). 69.12% were dissatisfied with administrative burden.

3.4. Income-Prestige. More than a half of participating anesthesiologists (55.3%) expressed satisfaction with their current income. One in every two were satisfied with their social status and the respect they have.

3.5. Personal Benefits. Most anesthesiologists (80.34%) declare they enjoy their work. Around a half believes that

Table 2: (a) Computed statistical parameters (mean, SD, and quartiles) along with frequencies for job situation in general and patient care aspects among surveyed anesthesiologists. (b) Computed statistical parameters (mean, SD, and quartiles) along with frequencies for each scoring referring to income-prestige among surveyed anesthesiologists.

(a)

Elements to be assessed	Statistical parameters			Computed frequencies for each scoring[a]
	Mean	SD	Quartiles	
Job situation in general	4.86	1.18	4; 5; 6	2 persons (1.47%) 3 persons (2.21%) 13 persons (9.56%) 21 persons (15.44%) 58 persons (42.65%) 33 persons (24.26%) 6 persons (4.41%)
Patient care	4.46	1.25		
Autonomy in treating patients	4.43	1.45	3; 5; 5	4 persons (2.94%) 11 persons (8.09%) 27 persons (19.85%) 10 persons (7.35%) 53 persons (38.97%) 26 persons (19.12%) 5 persons (3.68%)
Quality of care one can provide	4.50	1.31	3; 5; 5	2 persons (1.47%) 9 persons (6.62%) 27 persons (19.85%) 10 persons (7.35%) 58 persons (42.65%) 29 persons (21.32%) 1 person (0.74%)
Burden	3.01	1.04		
Workload	3.63	1.56	3; 3; 5	13 persons (9.56%) 19 persons (13.97%) 42 persons (30.88%) 13 persons (9.56%) 33 persons (24.26%) 13 persons (9.56%) 3 persons (2.21%)
Time available for family, friends, or leisure	3.09	1.44	2; 3; 4	16 persons (11.76%) 35 persons (25.74%) 47 persons (34.56%) 6 persons (4.41%) 24 persons (17.65%) 7 persons (5.14%) 1 person (0.74%)
Work-related stress	2.49	1.23	1; 2; 3	38 persons (27.94%) 31 persons (22.79%) 36 persons (26.47%) 26 persons (19.12%) 3 persons (2.21%) 2 persons (1.47%) None (0.00%)

(a) Continued.

Elements to be assessed	Statistical parameters			Computed frequencies for each scoring[a]
	Mean	SD	Quartiles	
Administrative burden	2.85	1.47	2; 3; 4	27 persons (19.85%) 38 persons (27.94%) 29 persons (21.33%) 20 persons (14.71%) 15 persons (11.03%) 6 persons (4.41%) 1 person (0.74%)

[a]1: extremely dissatisfied; 2: dissatisfied; 3: rather dissatisfied; 4: neither dissatisfied nor satisfied; 5: rather satisfied; 6: satisfied; 7: extremely satisfied.

(b)

Elements to be assessed	Statistical parameters			Computed frequencies for each scoring[a]
	Mean	SD	Quartiles	
Income-prestige	4.31	1.06		
Current income	4.20	1.38	3; 5; 5	5 persons (3.68%) 12 persons (8.82%) 30 persons (22.06%) 14 persons (10.29%) 55 persons (40.44%) 19 persons (13.97%) 1 person (0.74%)
Social status and respect	4.43	1.18	4; 4.5; 5	None (0.00%) 7 persons (5.15%) 25 persons (18.38%) 36 persons (26.47%) 41 persons (30.15%) 25 persons (18.38%) 2 persons (1.47%)
Personal rewards	4.59	1.11		
Intellectual stimulation	4.25	1.37	3; 4; 5	3 persons (2.21%) 15 persons (11.03%) 20 persons (14.70%) 34 persons (25.00%) 37 persons (27.21%) 25 persons (18.38%) 2 persons (1.47%)
Opportunity for continuing medical education	4.29	1.41	3; 5; 5	1 person (0.74%) 16 persons (11.76%) 30 persons (22.06%) 17 persons (12.50%) 42 persons (30.88%) 27 persons (19.85%) 3 persons (2.21%)
Enjoyment of work	5.21	1.14	5; 5; 6	1 person (0.74%) 3 persons (2.21%) 7 persons (5.15%) 16 persons (11.76%) 48 persons (35.29%) 50 persons (36.76%) 11 persons (8.09%)

(b) Continued.

Elements to be assessed	Statistical parameters			Computed frequencies for each scoring[a]
	Mean	SD	Quartiles	
Professional relations	5.25	0.98		
Relations with peers	5.10	1.23	5; 5; 6	2 persons (1.47%) 5 persons (3.68%) 9 persons (6.61%) 13 persons (9.56%) 47 persons (34.56%) 53 persons (38.97%) 7 persons (5.15%)
Relations with nurses and other staff	5.40	0.98	5; 6; 6	1 person (0.74%) None (0.00%) 5 persons (3.68%) 13 persons (9.56%) 46 persons (33.82%) 61 persons (44.85%) 10 persons (7.35%)

[a]1: extremely dissatisfied; 2: dissatisfied; 3: rather dissatisfied; 4: neither dissatisfied nor satisfied; 5: rather satisfied; 6: satisfied; 7: extremely satisfied.

the prospects for further education and professional development are good. 47.06% were satisfied with intellectual stimulation they gain at work.

3.6. Professional Relations. 78.78% were satisfied with the relations with their peers and 86.02% with the relations with nurses and other staff.

3.7. Relation to Sociodemographics and Life Satisfaction. Job satisfaction in general had strongest correlation with health status and predicted future followed by social life and economic status. Statistically significant ($P < 0.001$) correlation was found between satisfaction with social life ($r = 0.40$), health status ($r = 0.30$), and burnout, with time available for friends and family being the most important factor. Outlooks for the future (predicted future) were significantly ($P < 0.001$) influenced by health status, income, intellectual stimulation at work, and work enjoyment.

In our analysis, working hours were associated with the perceived burden level. Burnout level was significantly higher in anesthesiologists who worked more than 60 hours a week (Table 3). They assessed their health status and social and family life ($P \leq 0.05$) as significantly worse than the physicians who work shorter (Table 4). Those working more than 20 years gave a less favourable assessment of their career outlooks (predicted future) and family and social life ($P \leq 0.05$).

No statistically significant differences were found between men and women in the examined group. Different aspects of job satisfaction were also not influenced by marital status, place of residence, years since graduation, and number of jobs (employment places).

4. Discussion

The overall job satisfaction level among anesthesiologists in our study is comparable to the findings of other studies in different countries and is estimated at around 71–75% [5–7]. Our results demonstrate that anesthesiologists working longer hours are more prone to burnout and are more likely to be dissatisfied with different aspects of life (except family life). This trend is progressive with age.

Some studies point to more demanding family life responsibilities and discrimination in the work environment as causes for a lower satisfaction level and greater work-related stress issues among women. Others, including ours, cannot confirm these findings on the basis of observed survey results [8, 9]. No differences in any of the examined aspects of job satisfaction between participants with various length of service have been recorded, which were observed elsewhere in Europe [5, 10, 11].

The main positive determinants of job satisfaction among Polish anesthesiologists, similar to their Finnish and Swiss counterparts, were the quality of care one can provide and autonomy in patient treatment [5, 11]. Most anesthesiologists are content with their income levels. This is, however, at the expense of long working hours, often exceeding the EU norms. According to a report by the Ministry of Health, based on questionnaires obtained from 384 hospitals, the average monthly gross income of a senior specialist anesthetist in mid-2008 was 7211 PLN. Basic salary usually constitutes a half of the total income, the rest being earnings for staying on duty. Self-employed doctors earn up to 300% more. They often stay on duty eight days a month, with record breakers even as many as 20. This is where the earnings of more than 15000 PLN, declared by half of them, come from. More than 83% of doctors work longer than allowed by

Table 3: Sociodemographic discrete predictors (along with corresponding P values) of each scoring referring to job satisfaction in general, patient care, burden, income-prestige, personal rewards, and professional relations among surveyed anesthesiologists.

Sociodemographic variables/predictors[a]	Surveyed "dimensions" of work satisfaction					
	Job satisfaction in general	Patient care	Burden	Income-prestige	Personal rewards	Professional relations
Gender	(NS[b])	(NS[b])	(NS[b])	(NS[b])	(NS[b])	(NS[b])
(i) Male	4.89	4.44	3.11	4.20	4.56	5.25
(ii) Female	4.83	4.49	2.93	4.42	4.61	5.24
Marital status	(NS[b])	(NS[b])	(NS[b])	(NS[b])	(NS[b])	(NS[b])
(i) Single	4.89	4.51	2.89	4.19	4.44	5.29
(ii) Married	4.85	4.45	3.06	4.36	4.64	5.23
Place of living	(NS[b])	(NS[b])	(NS[b])	(NS[b])	(NS[b])	(NS[b])
(i) Big city (>20 000 citizens)	4.84	4.38	2.94	4.13	4.48	5.18
(ii) Small town (<20 000 citizens)	4.80	4.64	3.11	4.43	4.73	5.23
(iii) Rural area	5.20	4.13	2.95	4.60	4.44	5.60
Years since graduation	(NS[b])	(NS[b])	(NS[b])	(NS[b])	(NS[b])	(NS[b])
(i) ≤10	5.31	4.90	3.44	4.37	5.09	5.63
(ii) 11–20	5.04	4.24	3.14	4.37	4.39	5.39
(iii) 21–30	4.57	4.23	2.69	4.05	4.47	4.90
(iv) >30	4.83	4.64	3.08	4.61	4.51	5.36
Working hours	(NS[b])	(NS[b])	($P < 0.001$)	(NS[b])	(NS[b])	(NS[b])
(i) ≤60	4.95	4.54	3.30	4.39	4.63	5.31
(ii) >60	4.73	4.37	2.61	4.20	4.52	5.16
Number of employment places	(NS[b])	(NS[b])	(NS[b])	(NS[b])	(NS[b])	(NS[b])
(i) One	4.85	4.49	3.11	4.29	4.50	5.13
(ii) Two or more	4.87	4.44	2.92	4.34	4.67	5.37

[a]One-way ANOVA or test for trend across ordered groups has been carried out when appropriate.
[b]NS: (statistically) not significant.

the EU standards [12]. One in ten doctors works continuously for more than 13 hours a day (also on weekends) and one in twenty even as long as 18 hours. Often doctors work continuously for more than 30 hours (staying on duty for 24 hours and then the standard 8-hour working day), especially in smaller, understaffed hospitals [13]. Anesthesiologists usually earn more but work longer as well. In 2011 the basic salary among senior anesthesiologists, without any extra income for staying on duty, was between 2499 PLN and 11500 PLN, median: 4080 PLN (83% of respondents). Self-employed anesthesiologists earned between 26 PLN/h and 120 PLN/h in public hospitals, median: 67 PLN/h, and between 45 PLN/h and 200 PLN/h in private hospitals, median: 94,5 PLN/h. Anesthesiologists who completed the questionnaire in the ministry's study declared they had to work continuously for 24 hours 6 times a month on average; their mean working time was 267 hours a month, which is in line with the data on anesthesiologists' working time we obtained in our study [14].

Anesthesiologists are exposed to greater levels of stress than normative groups and as a result more frequently engage in alcohol and drug abuse, suffer from mental disorders, and find it more difficult to reconcile work with family life [15–18].

In Poland and Germany anesthesiologists experience more stress and are at a greater risk of burnout than general practitioners [3, 19]. Stress is caused by the responsibility for providing safe and high quality medical services, dealing with challenging medical situations, and making ethically and therapeutically difficult decisions, which anesthesiologists face every day. Working in the operating theatre, the ICU, making preoperative assessment, treating chronic and acute pain, or working in an emergency department anesthesiologists provide services for as many as 50–60% of hospitalized patients [20, 21]. That is why the proportion of the amount of workload, both with patients and with administrative burden, to leisure time remains unsatisfactory. Although data differs by country, it is estimated that as many as 25% of anesthesiologists are in the burnout high risk group [11, 22–24]. Authors of the study conducted among perioperative clinicians in the United States reported higher burnout scores in physicians than nurse anesthetists and the highest ones among residents [9]. Young anesthesiologists during their training are more prone to burnout and depression compared to people of similar age but different specialization. Surveys conducted in Turkey and the United States also revealed that anesthesiologists, especially without support from the family, are more likely to report suicidal thoughts [18, 25].

Good peer relations have been proven to reduce probability of burnout. Although most participants of our study described their relations with other medical staff as positive,

Table 4: Sociodemographic discrete predictors (along with corresponding P values) of analyzed aspects of life in surveyed anesthesiologists.

Sociodemographic variables/predictors[a]	Aspects of life				
	Material status	Health status	Predicted future	Social life	Family life
Gender	(NS[b])	(NS[b])	(NS[b])	(NS[b])	(NS[b])
(i) Male	5.25	5.32	4.66	4.66	5.45
(ii) Female	5.32	5.07	4.45	4.14	5.06
Marital status	(NS[b])	(NS[b])	(NS[b])	(NS[b])	($P = 0.001$)
(i) Single	5.20	5.14	4.51	4.43	4.57
(ii) Married	5.32	5.15	4.56	4.45	5.48
Place of living	(NS[b])	(NS[b])	(NS[b])	(NS[b])	(NS[b])
(i) Big city (>20 000 citizens)	5.13	5.15	4.58	4.42	5.10
(ii) Small town (<20 000 citizens)	5.32	5.20	4.58	4.36	5.44
(iii) Rural area	5.80	4.93	4.33	4.40	5.07
Years since graduation	(NS[b])	($P = 0.011$)	($P < 0.001$)	($P = 0.002$)	($P = 0.028$)
(i) ≤10	5.46	5.69	5.31	5.38	5.77
(ii) 11–20	5.39	5.30	4.70	4.48	5.61
(iii) 21–30	5.12	4.80	4.24	4.02	4.80
(iv) >30	5.33	4.76	4.36	4.14	5.25
Working hours	(NS[b])	($P = 0.025$)	(NS[b])	($P = 0.008$)	($P = 0.015$)
(i) ≤60	5.39	5.31	4.60	4.74	5.50
(ii) >60	5.14	4.91	4.48	3.89	4.88
Number of employment places	(NS[b])	(NS[b])	(NS[b])	(NS[b])	(NS[b])
(i) One	5.28	5.06	4.43	4.40	5.38
(ii) Two or more	5.29	5.24	4.68	4.38	5.10

[a]One-way ANOVA or test for trend across ordered groups has been carried out when appropriate.
[b]NS: (statistically) not significant.

anesthesiologists often have to deal with a lack of positive feedback from patients and colleagues. This can be attributed to the fact that anesthesiologists in the operating theatre are often perceived as mere comfort providers for surgeons, rather than critical elements of the process they are in practice.

Anesthesiologists evaluated their overall situation at work more favourably than primary care physicians (4.72) in Poland. Participants of our study, however, viewed their social status as lower and believed they received less respect from other people than general practitioners. Indeed, research carried out among patients and their relatives in Polish hospitals reveals that more than 2/3 of patients do not know what the work of an anesthesiologist involves and that anesthesiologists are doctors [26]. Despite the threat of stress and burnout most anesthesiologists are more satisfied with their jobs than GPs.

High job satisfaction levels among doctors reduce their susceptibility to burnout and mental disorders. Dissatisfied medical staff are more prone to burnout which decreases patient safety. A satisfied doctor is more committed to work and more willing to make sacrifices, exhibits greater productivity levels and lowers labor costs, contributes to patient satisfaction, and is a prerequisite for a good work environment [27].

5. Conclusions

(1) Job dissatisfaction among anesthesiologists is caused by heavy stress exposure. Work enjoyment is a protective factor against dissatisfaction.

(2) Anesthesiologists are at a high risk for burnout, especially when working long hours.

(3) The situation of anesthesiologists in Poland could be improved by enforcing shorter working hours and lower stress exposure through the introduction of standards for medical practice.

Conflict of Interests

The authors declare that they have no conflict of interests.

Authors' Contribution

Ewelina Gaszynska designed the study, performed analysis and interpretation of data, and performed the statistical analysis; Tomasz Gaszynski collected data, participated in design of study, and helped to draft the paper; Franciszek Szatko conceived of the study, participated in its design and coordination, and helped to draft the paper; Michal

Stankiewicz-Rudnicki translated the paper into English; all authors have given final approval to the version to be published.

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Clinical Study

Total Intravenous Anaesthesia with High-Dose Remifentanil Does Not Aggravate Postoperative Nausea and Vomiting and Pain, Compared with Low-Dose Remifentanil: A Double-Blind and Randomized Trial

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The study was designed to investigate postoperative nausea and vomiting (PONV) in low- and high-dose remifentanil regimens for total intravenous anaesthesia (TIVA) in adult female patients with American Society of Anaesthesiologists physical status classification I undergoing local breast excision. Propofol and remifentanil 5 ng·mL^{-1} (L group) or 10 ng·mL^{-1} (H group) were administered for anaesthesia induction and maintenance. Propofol was titrated within range of 0.1 μg·mL^{-1} to maintain bispectral index (BIS) values between 40 and 60. Haemodynamic parameters during the intra- and postoperative periods and 24 h postoperative visual analogue scale (VAS) and PONV were evaluated. Each group with 63 patients was analyzed. The H group showed higher use of remifentanil and lower use of propofol, with similar recovery time. Mean systemic arterial blood pressure (MBP), heart rate, and BIS did not differ significantly before and after endotracheal intubation in the H group. However, significant increases in MBP and BIS were apparent in the L group. Postoperative VAS, PONV incidence and scale, and Rhodes index did not differ significantly between the two groups. In conclusion, TIVA with high-dose remifentanil did not aggravate PONV with similar postoperative pain, compared with low-dose remifentanil. Furthermore, high-dose remifentanil showed more haemodynamic stability after endotracheal intubation. This trial is registered with KCT0000185.

1. Introduction

Postoperative nausea and vomiting (PONV) is a major concern in patients undergoing general anaesthesia and may increase patient discomfort, delay discharge, and increase costs of care. Inhalational anaesthetic agents may be one of the many contributors to emesis [1]. Total intravenous anaesthesia (TIVA) is preferred to avoid PONV for patients undergoing general anaesthesia [2]. For improved haemodynamic and surgical states, the combination of propofol as a hypnotic agent and remifentanil as an analgesic agent is the most popular TIVA regimen [3–5].

Remifentanil is an esterase metabolized opioid with a rapid clearance, which is widely used in general anaesthesia, especially for outpatients [6]. As a result of rapid clearance, it is expected that remifentanil is associated with less PONV, even though opioid use is a risk factor of PONV. However, PONV with remifentanil has been inconsistent in clinical situations. Rama-Maceiras et al. reported that propofol with remifentanil had a lower incidence of PONV

and requirement for antiemetic drugs in patients undergoing plastic surgery, compared with fentanyl [7]. Mukherjee et al. reported that patients with TIVA using propofol and remifentanil experienced significantly less PONV with a reduced requirement for antiemetics, compared with balanced anaesthesia using propofol, isoflurane, and fentanyl in middle ear surgery, even though the initial pain score was higher in patients with TIVA using propofol and remifentanil [8]. On the contrary, Del Gaudio et al. reported no difference of PONV between remifentanil and fentanyl in target-controlled infusion (TCI) of propofol for elective supratentorial craniotomy [9]. Morino et al. identified remifentanil use during surgery as a risk factor for PONV [10]. Gaszynski et al. reported that morbidly obese patients receiving remifentanil had higher rates of PONV and postoperative pain, compared with patients treated with fentanyl or alfentanil during open Roux-en-y gastric bypass [11]. Additionally, there is a paucity of literature regarding PONV with different doses of remifentanil.

The study was designed to investigate PONV in low- and high-dose remifentanil regimens for TIVA in adult female patients with American Society of Anaesthesiologists physical status (ASA PS) classification I undergoing local breast excision. The intraoperative haemodynamic parameters and postoperative pain were also evaluated.

2. Materials and Methods

2.1. Study Population. The study was approved by the Institutional Review Board of Konkuk University Medical Center, Seoul, Korea (KUH1160020), and registered at http://cris.nih.go.kr/ (KCT0000185). Written informed consent was obtained from each patient and the study was conducted in a prospective, double-blind, and randomized fashion. Adult female patients with ASA PS classification I undergoing local excision of breast under admission were enrolled. Patients were excluded if the following criteria were present: (1) patient age < 20 years, (2) redo case, (3) concurrent other surgery, (4) allergy to egg or soybean oil, (5) history of drug abuse, (6) receiving current medications, and (7) demand of patient-controlled analgesia (PCA). The patients admitted at a day before the operation. The written informed consent for the study and the preoperative interview with anaesthesia permission were obtained from the investigators and the anaesthesiologists who were expected to participate in patient care and blind to the study, respectively, at the same day. They were delivered at the day of the operation when the patient was transferred to the reception room for the operation. And then, the registered nurse (RN) who did not participate in patient care and was blind to the study performed all randomization processes. The patients were allocated randomly to receive either propofol-low dose remifentanil (L group) or propofol-high dose remifentanil (H group) for TIVA through the random assignment, performed by the RN, using sealed envelopes with the options inside L or H before anaesthesia induction. The equal numbers of sealed envelopes with the options with L for L group and H for H group were included in a sealed envelope. When a patient was dropped out of the study, the sealed envelope with the same option for the patient was added into the sealed envelope. The randomization was ended when the sealed envelopes with the options inside L and H were run out. The RN also prepared the TCI devices for the study before anaesthesia induction.

All data were collected by trained observers who did not participate in patient care and were blinded to the study.

2.2. Anaesthetic Technique. The anaesthetic technique was standardized. The patient arrived at the operation room without premedication. After establishing routine systemic blood pressure monitoring and noninvasive patient monitoring (pulse oximetry, electrocardiography, and bispectral index (BIS)), anaesthesia was induced. The anaesthesiologists who participated in patient care but were blinded to the study were requested to anaesthetize the patients as described below. Lidocaine 0.5 $mg \cdot kg^{-1}$ was administered to decrease pain induced by propofol. An initial target concentration (effect-site, modified Marsh model with a k_{e0} of 1.21 min^{-1} [12]) of propofol 4 $\mu g \cdot mL^{-1}$ and the fixed target concentration (plasma site, Minto model [13, 14]) of remifentanil 5 $ng \cdot mL^{-1}$ (L group) or 10 $ng \cdot mL^{-1}$ (H group) were administered using two TCI devices. The target concentrations of remifentanil in the L and H groups were achieved by 10 min of administration and maintained during anaesthesia. The fixed target concentration of remifentanil, prepared with TCI according to randomization by the RN who participated in the patients' allocation for the study, was blinded to the anaesthesiologists by sealing the monitor of the TCI device. An initial target concentration of propofol was titrated more or less than 0.1 $\mu g \cdot mL^{-1}$ to maintain BIS values between 40 and 60. Rocuronium 0.6 $mg \cdot kg^{-1}$ was administered for muscle relaxation after loss of consciousness under the guidance of peripheral neuromuscular transmission monitoring. Endotracheal intubation was performed after 10 min from the start of operation of the TCI device for remifentanil with a train-of-four count of 0. After the induction of anaesthesia, patients were ventilated with 40% oxygen in air. The tidal volume was 6 $mL \cdot kg^{-1}$ of ideal body weight and positive end-expiratory pressure was not utilized. The respiratory rate was adjusted to keep the partial pressure of end-tidal carbon dioxide between 35 and 40 mmHg. Additional rocuronium was administered under the guidance of peripheral monitoring of neuromuscular transmission. Phenylephrine 30 μg (if mean systemic arterial blood pressure (MBP) was below 60 mmHg and heart rate (HR) was above 40 $beats \cdot min^{-1}$), ephedrine 4 mg (if MBP was below 60 mmHg and HR was below 40 $beats \cdot min^{-1}$), or atropine (if HR was below 40 $beats \cdot min^{-1}$) was injected to prevent hypotension or bradycardia. Phenylephrine was continuously infused if MBP was below 60 mmHg and was continued with repetitive phenylephrine injections. Nicardipine 0.5 mg was injected at systolic systemic BP above 180 mmHg or diastolic systemic blood pressure above 110 mmHg, and esmolol 30 mg was injected at MBP above 60 mmHg and HR above 110 $beats \cdot min^{-1}$ during anaesthesia after the target concentration of remifentanil 5 $ng \cdot mL^{-1}$ (L group) or 10 $ng \cdot mL^{-1}$ (H group) was achieved. TCIs of remifentanil and propofol were stopped, and ketorolac 0.5 $mg \cdot kg^{-1}$ was injected intravenously for postoperative pain

control at the end of the surgery. Residual neuromuscular paralysis was antagonized with neostigmine 0.05 mg·kg^{-1} and glycopyrrolate 0.01 mg·kg^{-1} under the guidance of peripheral neuromuscular transmission monitoring. After endotracheal extubation, patient was transferred to postanaesthetic care unit (PACU).

2.3. Measurement. At arrival at the operation room, MBP, HR, and BIS were measured as baseline values (T0) just before endotracheal intubation (T1), just after endotracheal intubation (T2), and on arrival at PACU (T3). In patients receiving phenylephrine, ephedrine, or atropine, total dose of phenylephrine, ephedrine, atropine, nicardipine, or esmolol was recorded.

Postoperative pain and PONV were evaluated by RN who was blinded to the study at the PACU and general ward. Pain was assessed using a visual analogue scale (VAS) ranging from 0 to 100 with 0 being no pain and 100 being the worst pain imaginable on arrival at the PACU (T3), 30 minutes after arrival at PACU (T4), 6 h after discharge from the PACU (T5), and 24 h after discharge from PACU (T6). Ketorolac 0.5 mg·kg^{-1} was administered intravenously on demand at the PACU for postoperative analgesia and recorded. PONV was assessed using a three-point ordinal scale (0 = none, 1 = nausea, 2 = retching, and 3 = vomiting) [15] at the same points. Nausea was defined as a subjectively unpleasant sensation associated with awareness of the urge to vomit. Retching was defined as the labored, spasmodic, and rhythmic contraction of the respiratory muscles without expulsion of gastric contents. Vomiting was defined as the forceful expulsion of gastric contents from the mouth. The existence of PONV was defined as nausea, retching, or vomiting. The severity of PONV from T4 to T5 and from T5 to T6 was evaluated using a modified Rhodes index [16]. Ondansetron 0.1 mg·kg^{-1} was intravenously given for antiemetic treatment on demand and recorded.

Total doses of remifentanil and propofol were recorded with the TCI devices. Anaesthesia time (from TCI start to discharge from operation room) and operation time (from skin incision to end of surgery) were recorded. Recovery time (from TCI stop to discharge from the operation room) was also recorded.

2.4. Statistical Analysis. From a pilot study with 20 female patients undergoing local excision of breast under TIVA with low-dose remifentanil and propofol, PONV incidence and scale and Rhodes index at T5 were 15% (six patients), 0.30 ± 0.47 and 1.10 ± 1.89, respectively. The primary and secondary outcomes were Rhodes index at T5 and PONV incidence at T5, respectively. A minimum detected difference of double-PONV incidence, -PONV scale, and -Rhodes index between the groups was considered to be of clinical significance. The sample sizes of 63, 28, and 33 were calculated with a power of 0.9 and an α value of 0.05.

The data was analyzed by the statistician who was blind to the study, using the program Statistical Package for the Social Sciences ver. 11.0. The intragroup changes in MBP, HR, PONV, and VAS over time were analyzed using an analysis of variance on ranks for repeated measurements (Friedmann) and if significant, a Tukey's test was performed to compare the variables with the baseline value. The values between the L and H groups were analyzed using an unpaired Chi-square test, Fisher's exact test, or Mann-Whitney Rank Sum test. All data were expressed as the number of patients or mean ± standard deviation. A value of $P < 0.05$ was considered statistically significant.

3. Results

One hundred and fifty-six patients were eligible for the study. Twenty-seven patients were excluded: 5 patients for redo case, 1 patient for another concurrent surgery, 1 patient for allergy to egg or soybean oil, 15 patients for receiving current medications, and 5 patients for demand of PCA. Two patients declined to participate. One patient in the H group withdrew at T6. Thus, total 126 patients with 63 patients for each group were included in the final analysis (Figure 1).

The demographic profiles were similar between the two groups. The H group showed a higher use of remifentanil (1894 ± 735 versus 1013 ± 436 μg; $P < 0.001$) and lower use of propofol (428 ± 138 versus 580 ± 294 mg; $P < 0.001$), but there was no significant difference in recovery time (13 ± 4 versus 14 ± 6 min; $P = 0.82$) (Table 1).

Concerning haemodynamic changes, MBP and HR at T0 and T3 were not significantly different between the two groups. MBP at T1 was not significantly different between the two groups, but significantly lower HR (58 ± 12 versus 66 ± 11 beats·min^{-1}; $P < 0.001$) and higher BIS (47 ± 5 versus 45 ± 3; $P = 0.04$) were evident in the H group at T1. MBP (74 ± 11 mmHg in H group versus 86 ± 19 mmHg in L group; $P < 0.001$), HR (61 ± 12 beats·min^{-1} in H group versus 70 ± 14 beats·min^{-1} in L group; $P < 0.001$), and BIS (48 ± 5 in H group versus 54 ± 5 in L group; $P < 0.001$) at T2 had significant differences between the two groups. The number of patients who needed vasopressors such as phenylephrine, ephedrine, and atropine and total doses of vasopressors were similar between two groups (Table 2). Vasodepressor like nicardipine and esmolol was not used in both groups during anaesthesia.

Concerning intragroup haemodynamic changes, MBP, HR, and BIS had no significant differences before and after endotracheal intubation (T1 and T2) in the H group, although significant differences were evident for MBP, HR, and BIS between T0 and T1 and between T0 and T2, respectively. MBP, except for HR and BIS, displayed significant differences before and after endotracheal intubation (T1 and T2) in the L group. Significant differences were evident in MBP, HR, and BIS between T0 and T1 and between T0 and T2, respectively (Figure 2).

Postoperative VAS and the number of analgesic treatments for postoperative analgesia on demand according to time had no significant difference between the two groups. The number of patients with PONV in the H group was one at T3, eight at T4, nine at T5, and seven at T6. The number of patients with PONV in the L group was one at T3, seven at T4, ten at T5, and four at T6. No significant difference of PONV incidence was evident. PONV scale, Rhodes index, and the number of antiemetic treatments with ondansetron

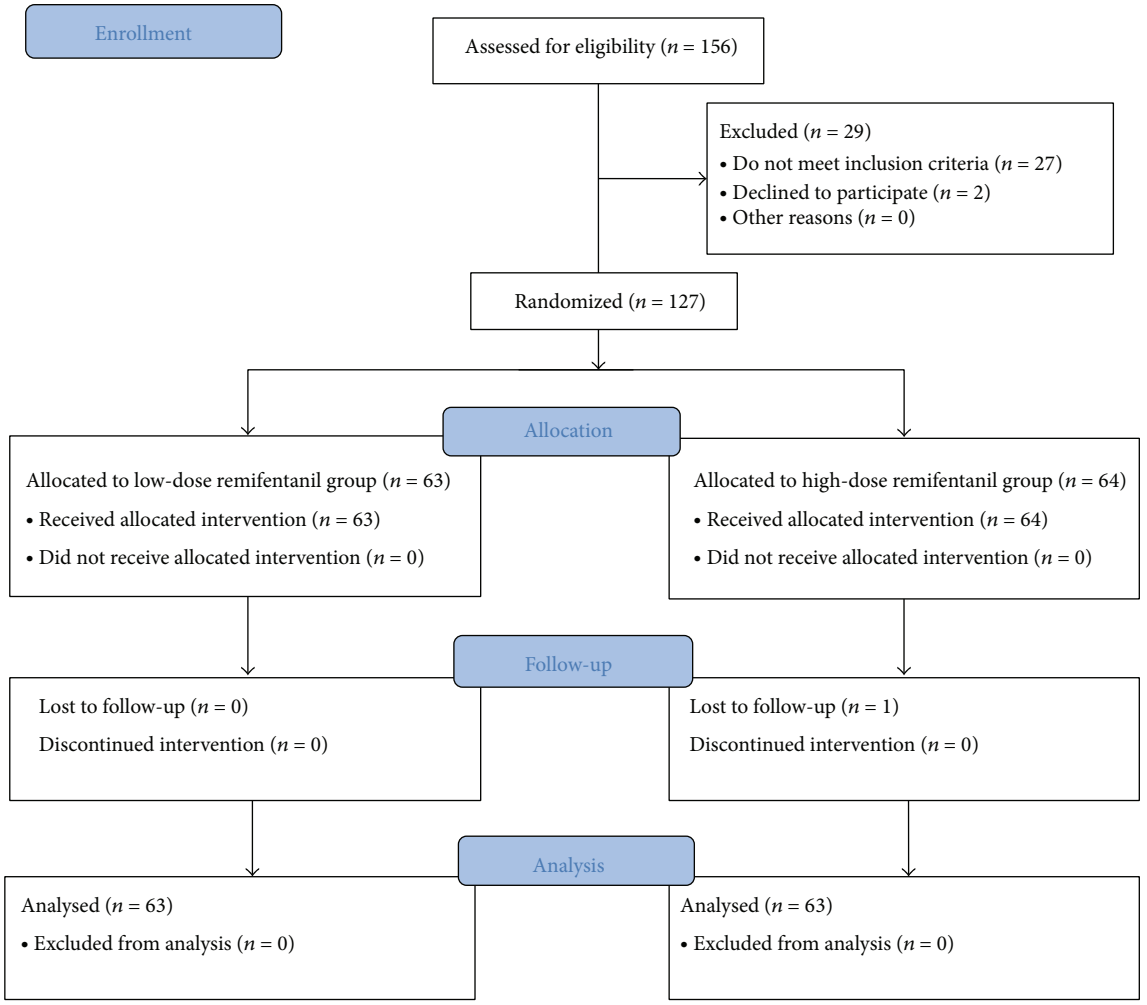

Figure 1: CONSORT flow diagram for the study.

Table 1: Demographic data from the L and H groups.

	L group (N = 63)	H group (N = 63)	P
Age (years)	47 ± 12	47 ± 9	0.95
Height (cm)	158 ± 7	158 ± 5	0.91
Weight (kg)	57 ± 10	58 ± 8	0.55
Smoking (pack × years)	0 ± 1	1 ± 4	0.64
Hx of motion sickness	4	7	0.34
Hx of PONV	1	1	1.00
Remifentanil (μg)	1013 ± 436	1894 ± 735	<0.001
Propofol (mg)	580 ± 294	428 ± 138	<0.001
Anaesthesia time (min)	104 ± 38	95 ± 35	0.15
Operation time (min)	69 ± 36	61 ± 33	0.23
Recovery time (min)	14 ± 6	13 ± 4	0.82

Values are expressed as number of patients or mean ± standard deviation.
L group: propofol-low dose remifentanil group; H group: propofol-high dose remifentanil group; Hx: history; PONV: postoperative nausea and vomiting.

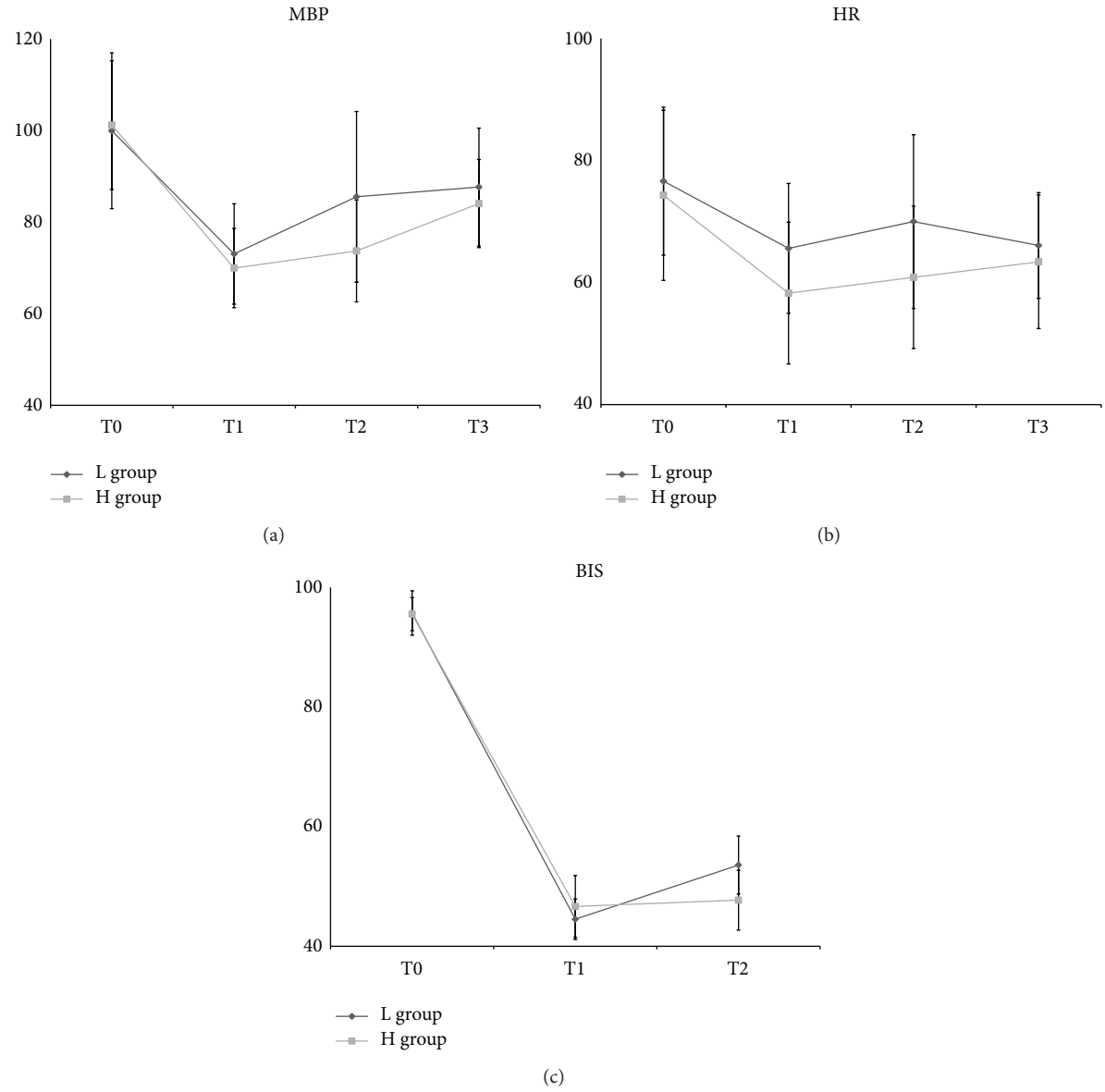

Figure 2: Haemodynamic changes according to time. (a) MBP: systemic mean blood pressure. (b) HR: heart rate. (c) BIS: bispectral index. L group: propofol-low dose remifentanil group; H group: propofol-high dose remifentanil group; T0: baseline value; T1: just before endotracheal intubation; T2: just after endotracheal intubation; T3: on arrival at postanesthetic care unit.

on demand according to time were not significantly different between the two groups (Table 3, Figures 3 and 4).

4. Discussion

No difference of PONV between low- and high-dose of remifentanil in adult female patients with ASA PS classification I undergoing local excision of breast under TIVA was evident.

Propofol is an antiemetic agent, although the mechanisms are not clear [17, 18]. Fujii and Nakayama showed that a low dose of propofol ($0.5\,mg{\cdot}kg^{-1}$) at the end of surgery is effective in preventing PONV during the first 24 h after anaesthesia in patients undergoing laparoscopic surgery [19]. Higher doses of propofol consumption were used in the present study (580 ± 294 mg in L group and 428 ± 138 mg in H group), including induction dose and dose for prevention of PONV. The PONV preventative concentrations of propofol in the blood or the effect-site have been unclear. However, continuous infusion of propofol with TCI might maintain the higher levels for longer time in the blood or the effect-site after the surgery, compared with two bolus doses of induction and small dose at the end of surgery, because the context-sensitive half time of propofol increases as the infusion time is lengthened [20]. Therefore, propofol combined with remifentanil in the present study might have prevented PONV in both groups although H group showed the lower consumption of propofol.

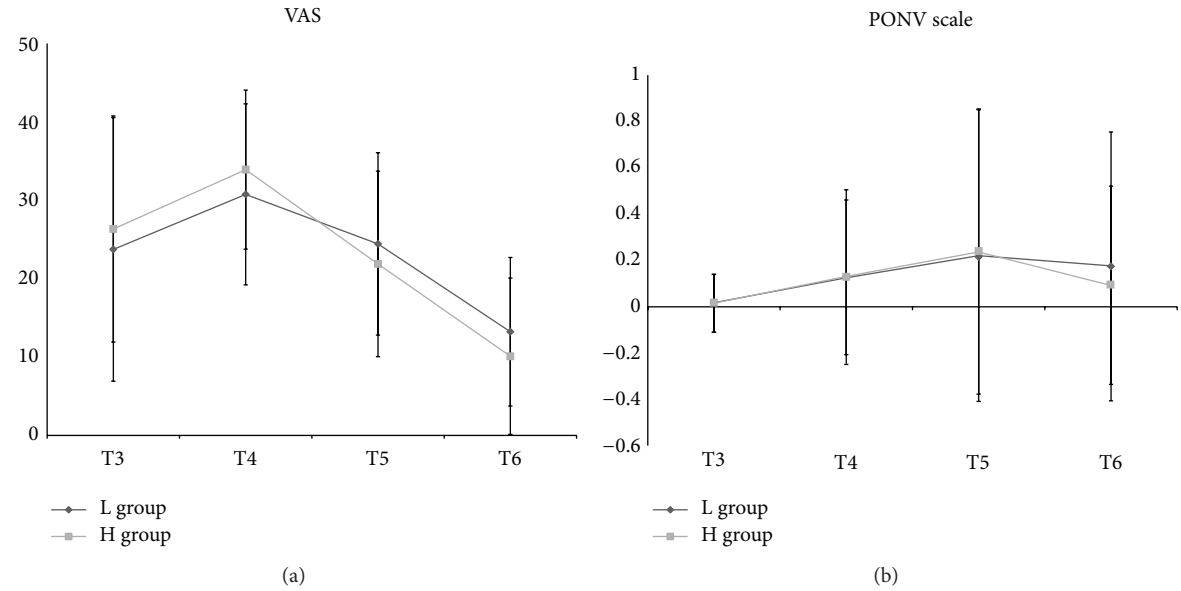

Figure 3: Postoperative pain and postoperative nausea and vomiting (PONV). (a) VAS: visual analogue scale. (b) PONV scale. L group: propofol-low dose remifentanil group; H group: propofol-high dose remifentanil group; T3: on arrival at postanesthetic care unit (PACU); T4: 30 min after arrival at PACU; T5: at 6 h after discharge from PACU; T6: at 24 h after discharge from PACU (T6).

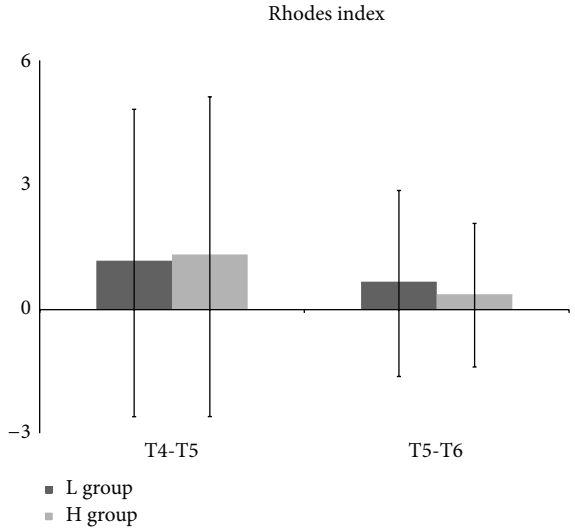

Figure 4: Severity of postoperative nausea and vomiting from 30 min after arrival at postanesthetic care unit (PACU) (T4) to 6 h after discharge from PACU (T5) and from 6 h after discharge from PACU (T5) to 24 h after discharge from PACU (T6) using Rhodes index. L group: propofol-low dose remifentanil group; H group: propofol-high dose remifentanil group.

Several studies have an association of high-dose remifentanil with acute intolerance associated with high VAS score and the need for more analgesic agents [21, 22]. However, presently, postoperative VAS during the first 24 h after operation was not significantly different between the two groups. At first, the pain after local excision of breast was not severe in the L group and the injection of ketorolac at the end of the surgery might almost cover the postoperative pain with or without remifentanil-induced hyperalgesia, although some patients needed rescue ketorolac. Secondly, acute tolerance occurs with even a low-dose of remifentanil [23], but it has remained unclear whether the intensity of acute tolerance is dependent on the dose of remifentanil, or not. If remifentanil-induced hyperalgesia occurred in the present study, it would be observed in both groups, regardless of intensity. Therefore, the pain severity would not differ between two groups if the injected ketorolac relieved the postoperative pain. Thirdly, propofol delays and weakens the antianalgesic effect of remifentanil through various pathways [24–27]. Shin et al. reported that remifentanil-induced hyperalgesia was apparent with sevoflurane but not with propofol [28]. The total amounts of propofol were different between the two groups, but all patients in both groups were sedated with a continuous infusion of propofol. This might have led to the abolishment of the difference of pain severity between two groups in the present study. If an inhalational agent as a hypnotic agent was used in the present study, the result may well have been different.

One consideration remains. Gaszynski et al. did not explain the reason for the association of higher rate of PONV and postoperative pain with remifentanil bolus dose of 1 $\mu g \cdot kg^{-1}$ for intubation and continuous infusion of 0.25–1.50 $\mu g \cdot kg^{-1} \cdot min^{-1}$ in morbidly obese patients during open Roux-en-y gastric bypass [11]. Morbidly obese patients were not included in the present study. Although the higher concentration of remifentanil in the study of Gaszynski et al., compared with that in the present study, was associated with higher rates of PONV and postoperative pain, morbidly obese patients should have been included to generalize the results of the present study.

Bradycardia and hypotension are commonly encountered adverse effects of TIVA with remifentanil and propofol.

Table 2: Haemodynamic parameters and bispectral index during anaesthesia.

	L group	H group	P
T0			
MBP (mmHg)	100 ± 17	101 ± 14	0.66
HR (beats·min^{-1})	77 ± 12	74 ± 14	0.17
BIS	96 ± 4	96 ± 3	0.18
T1			
MBP (mmHg)	73 ± 11	70 ± 9	0.13
HR (beats·min^{-1})	66 ± 11	58 ± 12	<0.001
BIS	45 ± 3	47 ± 5	0.04
T2			
MBP (mmHg)	86 ± 19	74 ± 11	<0.001
HR (beats·min^{-1})	70 ± 14	61 ± 12	<0.001
BIS	54 ± 5	48 ± 5	<0.001
T3			
MBP (mmHg)	88 ± 13	84 ± 10	0.09
HR (beats·min^{-1})	66 ± 9	63 ± 11	0.13
BIS	—	—	—
Vasopressor			
Phenylephrine			
Incidence	16/63	16/63	1.00
Dosage (μg)	27 ± 101	31 ± 116	0.98
Ephedrine			
Incidence	2/63	2/63	1.00
Dosage (μg)	0.13 ± 0.71	0.19 ± 0.86	0.88
Atropine			
Incidence	9/63	13/63	0.35
Dosage (μg)	0.07 ± 0.18	0.10 ± 0.20	0.65
Vasodepressor			
Nicardipine (mg)	—	—	—
Esmolol (mg)	—	—	—

Values are expressed as mean ± standard deviation or number of patients.
L group: propofol-low dose remifentanil group; H group: propofol-high dose remifentanil group; T0: baseline value; T1: just before endotracheal intubation; T2: just after endotracheal intubation; T3: on arrival at postanesthetic care unit; MBP: mean systemic arterial blood pressure; HR: heart rate; BIS: bispectral index.

The decrease of HR and MBP was also evident in the present study, regardless of the dose of remifentanil, with no similar total doses of phenylephrine, ephedrine, and atropine, although the extent of the decreases of HR and MBP was greater in the H group. However, the rise of HR and MBP after endotracheal intubation was observed only in the L group. The most important reason to use opioid in anaesthesia induction is to blunt sympathetic activations after endotracheal intubation and achieve haemodynamic stability. An adequate dose of opioid use without over- or under-dose is critical for the purpose. The H group showed more haemodynamic stability after endotracheal intubation than the L group, although no patient received nicardipine or esmolol to blunt sympathetic activations after endotracheal intubation in either group. Additionally, an intense stimulus, such as endotracheal intubation, significantly increased BIS in the L group indicating the possibility of intraoperative awareness at endotracheal intubation because of inadequate analgesia, although BIS before endotracheal intubation was in a tolerable general anaesthetic range between 40 and 60.

5. Conclusions

TIVA with high-dose remifentanil did not aggravate PONV with similar postoperative pain in adult female patients with ASA PS classification I undergoing local breast excision, compared with low-dose remifentanil. Furthermore, high-dose remifentanil showed more haemodynamic stability after endotracheal intubation than low-dose remifentanil.

Conflict of Interests

The authors declare that there is no conflict of interests regarding the publication of this paper.

Table 3: Postoperative pain assessed by a visual analogue scale (VAS) and postoperative nausea and vomiting (PONV).

	L group	H group	*P*
T3			
VAS	24 ± 17	26 ± 14	0.37
PONV incidence	1	1	1.00
PONV scale	0.02 ± 0.13	0.06 ± 0.13	1.00
Analgesic	4	3	0.70
Antiemetic	0	0	1.00
Rhodes index	—	—	—
T4			
VAS	31 ± 12	34 ± 10	0.06
PONV incidence	8	7	0.90
PONV scale	0.13 ± 0.34	0.13 ± 0.38	0.90
Analgesic	5	5	1.00
Antiemetic	0	0	1.00
Rhodes index	—	—	—
T5			
VAS	24 ± 12	22 ± 12	0.22
PONV incidence	9	10	0.88
PONV scale	0.22 ± 0.63	0.24 ± 0.62	0.88
Analgesic	2	0	0.15
Antiemetic	0	1	0.32
Rhodes index	1.11 ± 3.72	1.25 ± 3.86	0.88
T6			
VAS	13 ± 9	10 ± 10	0.06
PONV incidence	7	4	0.64
PONV scale	0.18 ± 0.58	0.10 ± 0.43	0.64
Analgesic	0	0	1.00
Antiemetic	0	0	1.00
Rhodes index	0.64 ± 2.25	0.35 ± 1.74	0.63

Values are expressed as mean ± standard deviation or number of patients.
L group: propofol-low dose remifentanil group; H group: propofol-high dose remifentanil group; T3: on arrival at post-anesthetic care unit (PACU); T4: after 30 minutes on arrival at PACU; T5: at 6 hours after discharge from PACU; T6: at 24 hours after discharge from PACU; PONV scale: PONV assessed using a three-point ordinal scale (0 = none, 1 = nausea, 2 = retching, and 3 = vomiting).

Authors' Contribution

Seong-Hyop Kim contributed to design of the study, collection of data, analysis and interpretation of data, and description of paper. Chung-Sik Oh contributed to the collection of data and analysis and interpretation of data. Tae-Gyoon Yoon, Min Jeng Cho, Jung-Hyun Yang, and Hye Ran Yi contributed to the collection of data.

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Review Article

A Review of Intraoperative Goal-Directed Therapy Using Arterial Waveform Analysis for Assessment of Cardiac Output

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Increasing evidence shows that goal-directed hemodynamic management can improve outcomes in surgical and intensive care settings. Arterial waveform analysis is one of the different techniques used for guiding goal-directed therapy. Multiple proprietary systems have developed algorithms for obtaining cardiac output from an arterial waveform, including the FloTrac, LiDCO, and PiCCO systems. These systems vary in terms of how they analyze the arterial pressure waveform as well as their requirements for invasive line placement and calibration. Although small-scale clinical trials using these monitors show promising data, large-scale multicenter trials are still needed to better determine how intraoperative goal-directed therapy with arterial waveform analysis can improve patient outcomes. This review provides a comparative analysis of the different arterial waveform monitors for intraoperative goal-directed therapy.

1. Introduction

There is increasing evidence that intraoperative fluid and hemodynamic management influence patient outcomes. It is a challenge for anesthesiologists to balance between administering intravenous fluid, vasoactive agents, or inotropic drugs to maintain appropriate cardiac output. Individualized goal-directed therapy (IGDT) utilizes hemodynamic parameters such as stroke volume, cardiac output, cardiac index, peripheral vascular resistance, blood pressure, and the variation of stroke volume to optimize volume status, myocardial contractility, and tissue perfusion. Previous studies have demonstrated that IGDT in the perioperative period can improve patient outcomes by decreasing postoperative recovery time, reducing postoperative complications, and shortening hospital length of stay, particularly in high-risk surgical patients [1–19].

Different monitoring techniques are available to evaluate stroke volume and cardiac output for IGDT intraoperatively. Since cardiac output is the principal determinant of tissue oxygen delivery, any monitoring technique used to guide fluid therapy should measure cardiac output [20]. One such technique is arterial waveform analysis, which evaluates stroke volume to calculate cardiac output and examines stroke volume variation to assess fluid responsiveness. While other intraoperative cardiac output monitors are available, such as pulmonary artery thermodilution and esophageal Doppler echocardiography, this review will focus on the use of intraoperative arterial waveform analysis for IGDT.

2. Methods

2.1. Basic Concepts of Arterial Waveform Analysis. Arterial waveform analysis is based on the relationship between blood pressure, stroke volume, arterial compliance, and vascular resistance. Different models and methods are used for the mathematical analysis of this waveform, one of them is the Windkessel model. This model originated from the Windkessel effect described in a circuit where there is an air chamber between a hand-operated pulsatile water pump and a water tube. As water is pumped periodically into the circuit, it compresses the air in the chamber which, in turn, pushes the water out of the chamber and into the circuit. The air chamber dampens the fluctuation of the water flow. The Windkessel effect can be observed in the human circulatory system when large elastic arteries distend as the blood pressure rises during systole and recoil as the pressure

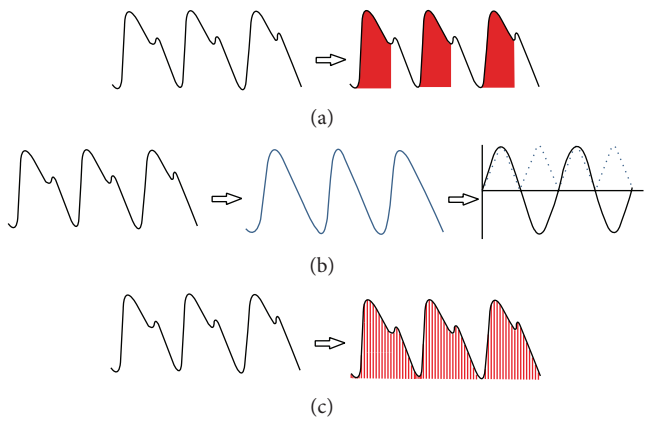

Figure 1: Different methods of arterial waveform analysis. (a) The PiCCO system utilizes the area under the curve of the systolic portion of the arterial waveform to calculate cardiac output, as depicted by the shaded area of the waveform on the right. (b) The LiDCO system uses pulse power analysis by first transforming the arterial waveform into a volume versus time waveform, as shown in the middle of the panel. Next, autocorrelation using a sine wave (solid black curve on the right of the panel) and a sine squared wave (dotted blue line on the right of the panel) estimates a nominal stroke volume, which can then be converted to cardiac output via calibration. (c) The FloTrac system samples multiple data points continuously, as depicted by the red lines. The standard deviation of the pressure data points around the mean arterial pressure is linearly related to stroke volume, which is then used to calculate cardiac output.

falls during diastole. The Windkessel effect dampens the fluctuation of blood pressure during the cardiac cycle and maintains organ perfusion during diastole. This model in human circulation is based upon two assumptions. The first is the conservation of mass principle, which states that the flow into a blood vessel must be equal to the outflow. The second assumption is that the compliance of the vessel affects its flow. During systole, the pressure in the blood vessel causes expansion and absorbs some blood because of the peripheral vascular resistance. During diastole, the pressure decreases and the stored blood is expelled. The peripheral vascular resistance and the capacitance of the arteries to store blood are the basis of the 2-element Windkessel model [21].

The 2-element Windkessel model is used for pulse contour analysis in the PiCCO (Pulsion Medical Systems, Munich, Germany) system. The cardiac output and aortic compliance are obtained by transpulmonary thermodilution via a central line. Once calibrated, the area under the systolic portion of the arterial pressure waveform is calculated on a beat-to-beat basis (Figure 1(a)). Because of the change in peripheral vascular resistance during monitoring, the system needs periodic recalibration for accurate stroke volume measurement [20, 22, 23].

The algorithm applied in the LiDCO (LiDCO, London, United Kingdom) system uses pulse power analysis rather than the shape of the arterial waveform. It is based on the assumption that the net power change in a heartbeat is dependent on the balance between the input of a mass of blood from stroke volume minus the blood lost to the periphery. Based on the conservation of mass and the correction for compliance, there is a linear relationship between net power and net flow. In this technique, the arterial pressure waveform is first converted into a volume waveform and then an autocorrelation technique is applied. This autocorrelation utilizes a continuous sine wave to describe the periodic motion of blood during a cardiac cycle and the root mean square of the sine waveform to describe a nominal stroke volume (Figure 1(b)). This volume is then converted to the actual stroke volume either by calibration or via comparison to a database as described below [20, 22, 23]. In the LiDCO device, a transfer function is used to relate peripheral pressures to central pressures. Because the peripheral pressure is measured directly, central pressure can be estimated with either a mathematical model or population data [24, 25].

The FloTrac (Edwards Lifesciences, Irvine, California) system provides an estimate of cardiac output using the standard deviation of the arterial pulse pressure around the mean arterial pressure and a conversion factor. The system samples data points at 100 Hz for 20 seconds to calculate the standard deviation of the pulse pressure. The conversion factor represents systemic vascular resistance, arterial compliance, body surface area, and biometric modifiers obtained from demographic data (Figure 1(c)). This algorithm does not require calibration because the conversion factor autocorrects for changing peripheral vascular resistance [20].

There is an additional method that utilizes pulse contour analysis and does not require preloaded data or calibration. It is called the MostCare (Vytech, Padova, Italy) system but because there are fewer validation studies with this system and no intraoperative trials, it is not included in this review [22].

2.2. Systems for Arterial Waveform Analysis. Four different systems are available to analyze the arterial waveform for monitoring cardiac output and guiding fluid therapy: FloTrac, LiDCO, PiCCO, and MostCare. As explained above, the MostCare system is not described in further detail in this review. The other three systems have been validated using comparisons to gold standard techniques for cardiac output monitoring, most commonly thermodilution with a

Table 1: Overview of the different arterial waveform analysis systems.

	FloTrac	LiDCO	PiCCO
Method of analysis	Standard deviation of arterial pulse pressure around the mean arterial pressure	Pulse power analysis	Pulse contour analysis
Calibration	Not needed	Manual—lithium dilution (not needed in LiDCO rapid)	Manual—thermodilution with saline or glucose
Requirements	Peripheral or central arterial	Peripheral or central arterial	Central arterial and central venous
Advantages	Minimally invasive, easy to use, and no calibration	Minimally invasive, easy to use, no calibration with LiDCO rapid, more accurate with hemodynamic instability, and waveform shape does not matter	More accurate with hemodynamic instability, additional data available (extravascular lung volume and intrathoracic blood volume)
Disadvantages	Not as reliable with hemodynamic instability since peripheral vascular resistance is included in the conversion factor	Not as accurate when patient receive lithium therapy or certain neuromuscular blocking agents	More invasive, shape of arterial waveform matters

pulmonary artery catheter. The systems are different in terms of invasiveness, calibration, and limitations (Table 1). These three systems have been used in randomized controlled trials to assess IGDT intraoperatively and its effect on patient outcomes. One important limitation of all the systems is that they do not perform reliably in hemodynamic instability, although the LiDCO and PiCCO systems may perform better in these situations [20].

2.2.1. The FloTrac System (*Edwards Lifesciences, Irvine, California*). The FloTrac system involves a FloTrac sensor and a Vigileo monitor and is also known as FloTrac/Vigileo. It requires a peripheral arterial line and it does not require calibration. There are currently three different software releases of the system. The software updates have improved the validity and reliability of the measurements. However, it is still unclear how reliable the system is in low systemic vascular resistance states, such as in patients with sepsis or in patients who are on concurrent vasopressor therapy [20, 24, 26, 27].

2.2.2. The LiDCO System (*LiDCO, London, UK*). The LiDCO system requires an arterial line and a calibration system using a lithium indicator dilution. With the new LiDCO plus system, recalibration is not necessary. Additionally, a LiDCO rapid version that consists of the previously described pulse power analysis algorithm and does not require calibration at all exists. The LiDCO rapid system is able to do this by the use of patient biometric data, including age, height, and weight, which serve as the calibration for the system [28]. One important limitation for the LiDCO systems requiring calibration is that, in patients receiving lithium therapy, the baseline lithium level will falsely elevate the calculated cardiac output. Moreover, neuromuscular blockers that have quaternary ammonium ions can disturb the lithium sensor and affect estimated cardiac output. Nonetheless, the LiDCO method has still been shown to be at least as reliable as other thermodilution techniques, and it also only requires a peripheral arterial line. Furthermore, because LiDCO does not use pulse contour analysis but rather employs pulse power analysis, the shape of the waveform is not as important. Additionally, the LiDCO system may be accurate in cases of hemodynamic instability although data are still inconclusive [20, 24, 26, 29].

2.2.3. The PiCCO System (*Pulsion Medical Systems, Munich, Germany*). The PiCCO system combines arterial waveform analysis with thermodilution techniques. It uses transpulmonary thermodilution, which requires both central venous and central arterial access (femoral, axillary, or brachial artery). External measurement of the cardiac output and the compliance of the aorta via thermodilution provide the calibration factor. The PiCCO system has been shown to be reliable when compared with a pulmonary artery catheter in a variety of situations and may even have good tracking of cardiac output in cases of hemodynamic instability, although data are still inconclusive. Additional benefits include more calculated data, such as extravascular lung water or intrathoracic blood volume. The major drawback of the PiCCO system is the requirement of central arterial and venous access as opposed to the LiDCO and FloTrac systems which require only peripheral arterial access. Additionally, there is no data to describe how often recalibration is needed [20, 24, 26, 39].

2.3. Article Search. This paper is an unsolicited review to determine if intraoperative IGDT applied by different systems using arterial waveform analysis improves patient outcomes

Table 2: Studies using IGDT with arterial waveform analysis intraoperatively.

Study authors	Analysis system	Type of study	Total number of patients	Outcomes
Benes et al. [30]	FloTrac	RCT	120	FloTrac group had significantly fewer postoperative complications. No difference in hospital length of stay or mortality was seen.
Mayer et al. [31]	FloTrac	RCT	60	FloTrac group had significantly fewer complications and a shortened median duration of hospital stay.
Cecconi et al. [32]	FloTrac	RCT	40	FloTrac group had a significant decrease in postoperative complications and received more dobutamine intraoperatively.
Scheeren et al. [33]	FloTrac	RCT	64	FloTrac group had significantly fewer postoperative wound infections. No significant difference in complications or ICU length of stay.
van der Linden et al. [34]	FloTrac	RCT	27	No difference in tissue oxygen delivery (main outcome measure).
Bisgaard et al. [35]	LiDCO	RCT	64	LiDCO group had higher stroke volume index and oxygen delivery index in postoperative period. No difference in number of complications or length of hospital stay.
Bisgaard et al. [36]	LiDCO	RCT	40	LiDCO group had increased stroke volume index, cardiac index, and oxygen delivery. Statistically significant decrease in complications in LiDCO group. No difference in the median length of hospital stay.
Wiles et al. [37]	LiDCO	RCT	128 (planned)	Ongoing. No available data.
Goepfert et al. [38]	PiCCO	RCT	100	PiCCO group had significantly fewer postoperative complications, decreased time to achieve ICU discharge criteria, and decreased length of ICU stay.

and when this technique should be employed. To gather appropriate articles about trials of intraoperative IGDT, a PubMed search was undertaken using search phrases coupling "goal-directed therapy" with "arterial waveform analysis" and with each of the three systems. This search provided forty articles. Articles that were randomized controlled trials were included for further analysis and the rest were excluded. This yielded a total of three articles for this review. In an effort to find more literature, all review articles from the original search were read and citations for further articles that were randomized controlled trials involving any of the three systems were reviewed. This technique gave an additional six articles for review, providing a total of nine trials.

3. Results

3.1. Trials of Intraoperative IGDT Using Arterial Waveform Analysis. Nine small-scale randomized controlled trials have been undertaken to examine patient outcomes when performing goal-directed therapy using arterial waveform analysis intraoperatively (Table 2). To date, no large-scale multicenter trials have been done.

3.1.1. FloTrac Trials. Benes et al. completed a small prospective randomized trial in high-risk surgical patients using the FloTrac system to optimize intraoperative fluid management. There were 60 patients in both the control and FloTrac groups, all of whom were scheduled for elective intra-abdominal surgery. The aim of this study was to maintain stroke volume variation less than 10% with colloid boluses of 3 mL/kg. Patients in the FloTrac arm had significantly fewer hypotensive events intraoperatively, lower lactate levels at the end of surgery, and fewer postoperative complications (18 versus 35 patients in the FloTrac and control groups, resp.). Severe complications (7 versus 22 patients in the FloTrac and control groups, resp.) and total complications (34 versus 77 patients in the FloTrac and control groups, resp.) were also significantly decreased. No difference in hospital length of stay or mortality was seen [30].

Mayer et al. had similar results in a separate small randomized controlled trial of high-risk surgical patients. This study had a total of 60 patients, 30 in each group, all scheduled for major abdominal surgery. The FloTrac system was used to maintain a cardiac index greater than 2.5 L/min/m^2 using either dobutamine or colloid boluses, depending on stroke volume index and stroke volume variation. In this study, significantly fewer patients developed complications in the FloTrac arm (6 versus 15). There was a significantly shorter median duration of hospital stay (15 days versus 19 days) in the FloTrac group compared to the control group [31].

Cecconi et al. performed a randomized controlled trial of goal-directed therapy using the FloTrac system in patients

undergoing elective total hip arthroplasty under regional anesthesia. This small-scale study included 20 patients each in the control arm and the FloTrac arm. In the FloTrac group, patients received colloid boluses until stroke volume increases were less than 10%. At that time, if oxygen delivery was not greater than 600 mL/min/m^2, dobutamine was started and increased to reach the oxygen delivery goal. Blood samples were taken every 30 minutes and hemoglobin concentration was maintained greater than 10 g/dL. Goal-directed therapy applied to these patients showed statistically significant decreases in postoperative complications in the FloTrac arm, although the number of complications was small in both groups. Patients in the FloTrac arm received more blood intraoperatively; however, the control group needed more transfusions postoperatively. Overall, the quantity of blood transfused was the same between the groups. The FloTrac arm did receive more dobutamine intraoperatively (11 of 20 patients versus 0 in the control arm) [32].

Scheeren et al. conducted a prospective, randomized multicenter study of high-risk surgical patients to evaluate FloTrac based intraoperative goal-directed therapy. The treatment group had stroke volume variation maintained at less than 10% with colloid boluses. The study included 64 patients undergoing high-risk surgery, with 32 patients enrolled in each arm. Postoperative wound infections were lower in the FloTrac group and this data reached statistical significance (0 patients versus 7 patients in the control group). There was a trend toward fewer complications in the FloTrac group, although this was not statistically significant in this study. Additionally, intensive care unit (ICU) length of stay tended to be shorter in the FloTrac group, but this was also not statistically significant [33].

Finally, van der Linden et al. performed a randomized controlled trial to evaluate the effectiveness of goal-directed therapy with the FloTrac system in patients undergoing peripheral arterial surgery. The main outcome measure for this study was tissue oxygen delivery. Cardiac index was to be maintained greater than 2.5 L/min/m^2 using colloid boluses initially and as long as cardiac index increased, this was maintained until central venous pressure was 15 mm Hg at which time dobutamine was initiated. The study had 3 different groups: group 1 underwent standard hemodynamic management with sevoflurane based general anesthesia, group 2 received goal-directed therapy with sevoflurane based general anesthesia, and group 3 was administered goal-directed therapy with propofol based general anesthesia. Patients assigned to goal-directed therapy with the FloTrac system received more dobutamine intraoperatively (2 patients in group 1, 13 patients in group 2, and 12 patients in group 3). None of the patients in the sevoflurane groups had postoperative cardiac complications but 4 of 20 patients in the propofol group had postoperative cardiac complications. In terms of tissue oxygen delivery, no differences between any of the groups were seen [34].

3.1.2. LiDCO Trials. There are a limited number of trials utilizing the LiDCO system for intraoperative goal-directed therapy. Pearse et al. conducted a randomized controlled trial for early goal-directed therapy using the LiDCO system following major surgery. There were 122 patients in this study, 62 patients in the treatment arm, and 60 patients in the control group. The goal of the treatment arm was to attain an oxygen delivery index of 600 mL/min/m^2 versus conventional management in the control group. The treatment group received more colloid and dopexamine to maintain oxygen delivery. Statistically significant findings included a reduction in complications and median duration of hospital stay. No difference in mortality was seen. Because this is a postoperative study, it is not included in Table 2 [40].

Bisgaard et al. performed a randomized controlled trial using LiDCO based goal-directed therapy in the perioperative period in patients undergoing open abdominal aortic surgery. 64 patients were enrolled in the study (32 in each group). LiDCO data was used prior to surgery and continued until 6 hours postoperatively. Stroke volume index was monitored and boluses of 250 mL of colloid were given in the LiDCO group to maintain stroke volume index intraoperatively. Postoperatively, colloid boluses were given and dobutamine was initiated if oxygen delivery did not reach 600 mL/min/m^2 after stroke volume index optimization. Stroke volume index and oxygen delivery index were higher in the postoperative period in the IGDT group; however, the number of complications and length of hospital stay did not differ between the groups [35].

A different study by Bisgaard et al. evaluated the use of goal-directed therapy in patients receiving lower limb arterial surgery. This study was also conducted from the start of surgery to 6 hours postoperatively. This study had 40 total patients with 20 patients each in the LiDCO group and the control group. The protocol in this study is the same as above. Boluses of 250 mL of colloid were given in the LiDCO group to maintain stroke volume index intraoperatively. Postoperatively, colloid boluses were given and dobutamine was initiated if oxygen delivery did not reach 600 mL/min/m^2 after stroke volume index optimization. Stroke volume index and cardiac index throughout the treatment period and postoperative oxygen delivery were improved for patients in the LiDCO group. Complications were significantly lower in the LiDCO group (5 of 20 patients) versus the control group (11 of 20 patients). There was no difference in the median length of hospital stay between the groups [36].

In addition to these studies, there is an additional study that is currently underway examining goal-directed therapy intraoperatively with the LiDCO system. Wiles et al. have proposed this study to look at patients undergoing hip fracture surgery who receive spinal anesthesia. The study has been approved and is registered but no data is currently available. The abstract methods state that the plan is to enroll a total of 128 patients [37].

3.1.3. PiCCO Trials. While the PiCCO system has been well validated, it has not been used in randomized clinical trials as much as the other methods of arterial waveform analysis. Goepfert et al. did utilize the PiCCO system in 100 patients undergoing coronary artery bypass grafting to determine if individualized therapy could improve outcomes. This

study was started intraoperatively and continued throughout the ICU course. Goal-directed therapy focused initially on maintaining stroke volume variation below 10% by use of intravenous fluids. Then, cardiac index was maintained at 2 L/min/m^2 either with heart rate increases via pacing if heart rate was less than 50 beats per minute or with epinephrine. Norepinephrine was given if the cardiac index was appropriate but the mean arterial pressure was less than 65 mm Hg. Statistically significant findings included patients in the treatment group ($n = 50$) having fewer postoperative complications than the control group ($n = 50$), 40 versus 63, taking less time to achieve ICU discharge criteria (15 hours versus 24 hours), and having shorter ICU stays (42 hours versus 62 hours), respectively [38].

4. Discussion

Many different tools now exist to help anesthesiologists measure cardiac output intraoperatively. For many years, we had relied only on data from pulmonary artery catheters. Arterial waveform analysis with FloTrac and LiDCO provides the option to use only a peripheral arterial line for cardiac output measurement. The PiCCO system offers an additional option if a central arterial line and a central venous line are placed. While no large multicenter studies exist for utilizing this new technology, small-scale studies suggest fewer complications and decreased hospital length of stay when anesthesiologists use arterial waveform analysis in the operating room to guide goal-directed therapy.

In light of recent evidence that goal-directed therapy improves patient outcomes, these early trials are not surprising but nonetheless provide an exciting new area of research. In addition to large-scale studies, parameters need to be defined to guide goal-directed therapy, including when and how much fluid to give and when to initiate inotropes. Moreover, not all patients would benefit from additional monitoring so more definition needs to be given to the specific patient populations and types of surgeries where arterial waveform analysis should be used. Additionally, more evidence is needed to decide if analysis should be done intraoperatively, postoperatively, or both.

Our experience with arterial waveform analysis for cardiac output monitoring in the intraoperative setting has included the LiDCO and FloTrac systems. A first generation LiDCO device was used to keep the cardiac index at the basal value, which was determined at the start of the case. This preliminary system did not provide stroke volume variation so the arterial waveform was monitored for significant amplitude variation. When this occurred, volume was administered to overcome pressure variation and hypotension. The first generation LiDCO system has significantly changed since that time, and we do not have experience with the current LiDCO models. We have, however, recently used the FloTrac system in major abdominal and vascular cases and monitored cardiac index and stroke volume variation to guide intraoperative fluid management.

Based on our experience, we do not currently see an advantage of one system over another. They both provide practitioners algorithms for hemodynamic management, which is the first step in optimizing the amount of fluid and vasoactive medications administered intraoperatively. Thus far, we have used various systems based primarily on availability and recommend that providers use whichever systems that are readily available and well understood. Our future steps include the implementation of prospective studies to better understand the use of arterial waveform analysis in specific patient populations, such as in patients with hypertension or decreased ejection fraction.

5. Conclusions

While there is a lack of large multicenter randomized controlled trials, preliminary small-scale studies indicate that utilizing intraoperative arterial waveform analysis to guide IGDT improves patient outcomes. These studies have shown fewer postoperative complications, fewer wound infections, and decreased hospital length of stay when arterial waveform analysis is used intraoperatively. The appropriate selection of a system can vary based on the patient, procedure type, and institutional variation, and more studies need to be completed to further define these parameters.

The FloTrac system seems to have the most data and is also the easiest to use for the fact that it requires only a peripheral arterial line and does not require calibration. The LiDCO system also requires only a peripheral arterial line; however, certain versions do require calibration. An added benefit is that the LiDCO system uses pulse power analysis and therefore does not rely on the shape of the arterial waveform. The PiCCO system is the most cumbersome as it requires both central arterial and central venous access as well as calibration. Studies have just begun with the PiCCO system so it is still unclear whether the benefits outweigh these disadvantages. An important aspect of this system that should be considered is that it provides additional information including extravascular lung water and intrathoracic blood volume, which can be important in critically ill patients.

Conflict of Interests

The authors have no conflict of interests.

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Clinical Study

A Comparison of Performance of Endotracheal Intubation Using the Levitan FPS Optical Stylet or Lary-Flex Videolaryngoscope in Morbidly Obese Patients

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Introduction. The use of videolaryngoscopes is recommended for morbidly obese patients. The aim of the study was to evaluate the Levitan FPS optical stylet (Levitan) vs Lafy-Flex videolaryngoscope (Lary-Flex) in a group of MO patients. *Methods.* Seventy-nine MO (BMI $> 40\,\mathrm{kg\,m^{-2}}$) patients scheduled for bariatric surgery were included in the study and randomly allocated to the Levitan FPS or Lary-Flex group. The primary endpoint was time to intubation and evaluation laryngoscopic of glottic view. Anesthesiologists were asked to evaluate the glottic view first under direct laryngoscopy using the videolaryngoscope as a standard laryngoscope (monitor display was excluded from use) and then using devices. The secondary endpoint was the cardiovascular response to intubation and the participant's evaluation of such devices. *Results.* The time to intubation was 8.572.66 sec. versus 5.790.2 sec. for Levitan and Lary-Flex, respectively ($P < 0.05$). In all cases of CL grade > 1 under direct laryngoscopy, the study devices improved CL grade to 1. The Levitan FPS produced a greater cardiovascular response than the Lary-Flex videolaryngoscope. *Conclusion.* The Lary-Flex videolaryngoscope and the Levitan FPS optical stylet improve the laryngeal visualization in morbidly obese patients, allowing for fast endotracheal intubation, but Lary-Flex produces less cardiovascular response to intubation attempt.

1. Introduction

Obesity is a rising problem amongst population health worldwide. The percentage of obese individuals in the Poland's population is about 12% but in western countries nears 60% [1]. Increased BMI is associated with an increased probability of difficult intubation [2]. This probability is 1.24 times higher with BMI 25–35 $\mathrm{kg\,m^{-2}}$ and 1.42 times higher with BMI $\geq 35\,\mathrm{kg\,m^{-2}}$ when compared to nonobese patients [2]. Other research suggests that the probability of difficult intubation is three times [3] or even six times [4] higher in obese patients compared to nonobese patients.

Laryngoscopy may be difficult in obese patients because of elevated chest diameter giving limited space for the laryngoscope positioning, limited neck mobility, and increased amount of fat tissue in the upper airway, including a larger tongue [5, 6]. Because of these challenges, it is recommended to properly position obese patients for intubation [7].

The use of videolaryngoscopes should improve laryngeal view in morbidly obese patients [8, 9]. Although obesity alone is not a risk factor for difficult intubation [10], it is recommended to use videolaryngoscopes as a part of routine practice in anesthesia for morbidly obese patients [11]. The Levitan FPS optical stylet (Clarus Medical, Minneapolis, USA) and

Lary-Flex videolaryngoscope (Acutronic, Switzerland) are portable devices for airway management (Figures 1 and 2). A limited number of scientific papers describe clinical experience with these devices in morbidly obese patients. To our knowledge, this is the first prospective randomized study comparing the use of Lary-Flex videolaryngoscope and Levitan FPS in morbidly obese patients.

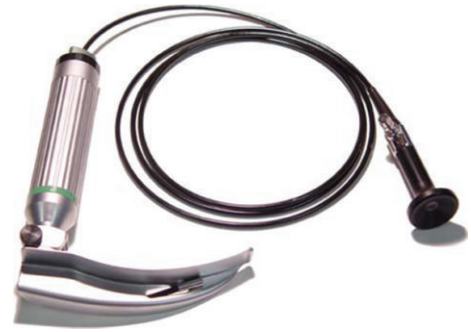

Figure 1: Lary-Flex videolaryngoscope (source: manufacturer marketing materials).

Figure 2: Levitan FPS optical stylet (source: manufacturer marketing materials).

2. Materials and Methods

The study protocol was approved by the Medical University of Lodz Ethics Committee (Protocol number: RNN/752/10/KB, Chairperson: Professor P. Polakowski, December 14, 2010). Eighty morbidly obese (BMI > 40 kg m^{-2}) patients scheduled for bariatric surgery were included into study after receiving written consent. Patients with predicted difficult intubation were excluded from the study: limited mouth opening < 3 cm, Mallampati grade > 3, neck circumflex > 50 cm, and thyromental distance < 6 cm [12]. Patients were randomly allocated to intubate with the Levitan optical stylet or Lary-Flex videolaryngoscope (Figure 3).

For intubation, patients were situated in the head-elevated position [13]. All patients were anesthetized following our institution protocols: induction of anesthesia with propofol 2.0 mg kg^{-1} of corrected body weight; for muscle relaxation rocuronium 0.6 mg kg^{-1} of ideal body weight (IBW); fentanyl 0.05 mg kg^{-1} of IBW. After achieving 100% neuromuscular suppression confirmed by TOF-Watch monitoring, laryngoscopy was performed by various anesthesiologists with ranging degrees of videolaryngoscope experience. All have been working at least few years in the University Hospital Bariatric Centre. Intubation in each patient, allocated to the Levitan group, was facilitated with the use of a laryngoscope and Macintosh-shaped blade. In the Lary-Flex group, intubation was facilitated using videolaryngoscopes as a standard laryngoscope (the monitor display was excluded from use) while also evaluating the glottic view under direct laryngoscopy (C/L 1). Afterwards they were asked to look at the monitor of the videolaryngoscope and facilitate patient intubation (C/L 2). The laryngoscopic conditions were evaluated using the Cormack-Lehane scale. In the Levitan group, anesthesiologists were asked to evaluate the laryngoscopic view using a standard Macintosh blade laryngoscope (C/L 1) and then intubate patient using Levitan FPS optical stylet (C/L 2). Intubation conditions were evaluated using the Krieg scale (Table 1): K1 in the Levitan group using only laryngoscope and in Lary-Flex group using videolaryngoscope as standard laryngoscope and K2 using Levitan FPS and using the whole videolaryngoscope set.

The time from placing the laryngoscope in the hand to insertion of the endotracheal tube was recorded using the same stopwatch in every case and the number of attempts was recorded. Failed intubation was defined as esophageal intubation or intubation attempt taking longer than 30 seconds. Cardiovascular parameters were recorded before intubation (T1) and during intubation (T2) based on the cardiovascular response to intubation. Subsequent to intubation, participants evaluated whether the devices studied aided intubation conditions or not.

Table 1: Krieg scale.

Score	1	2	3	4
Laryngoscopy	Easy	Good	Difficult	Impossible
Vocal cords	Open	Move	Closing	Closed
Coughing reflex	Absent	Diaphragm move	Weak	Strong

Evaluation of intubation conditions: 3-4: ideal; 5-6: good; 8–10: poor; 10–12: difficult.

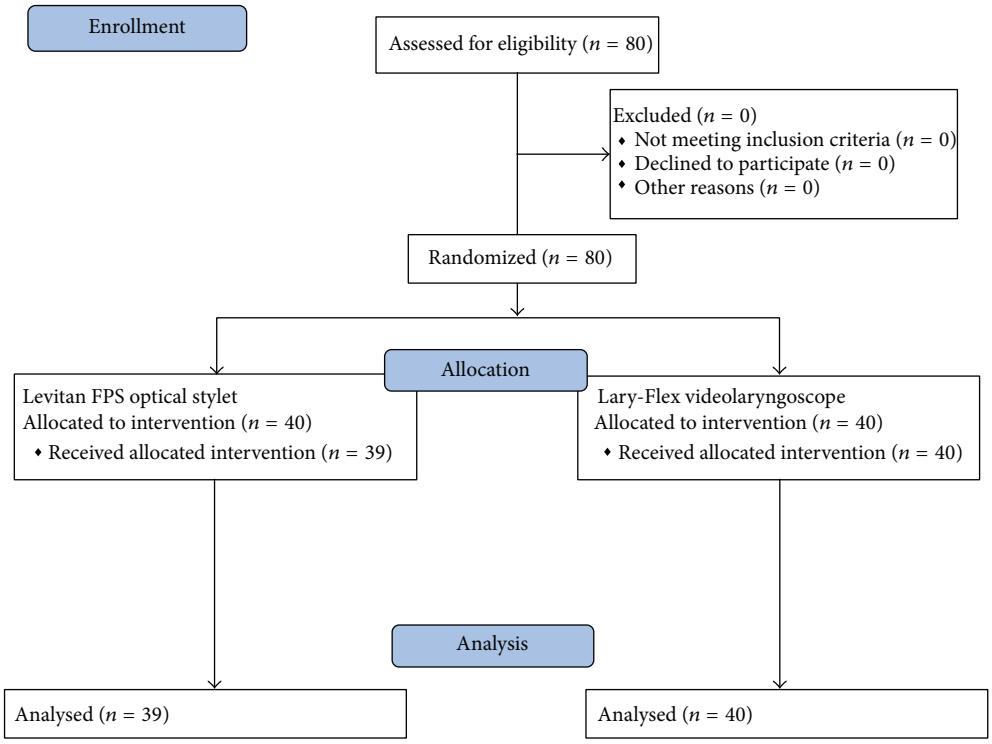

Figure 3: Flow diagram for the study.

Table 2: Demographic data of studied groups.

Group	Parameter	N	Mean	95% CI		Median	Minimum	Maximum	Q1	Q3	SD	SE	P group Levitan versus Lary-Flex
Levitan	Age (yrs)	40	40.10	36.57	43.63	39.00	19.00	60.00	32.50	48.50	11.05	1.75	0.307822
	Weight (kg)	40	126.03	119.43	132.62	123.00	100.00	200.00	109.50	139.00	20.63	3.26	0.968712
	Height (cm)	40	168.03	165.21	170.84	165.50	154.00	190.00	163.00	172.00	8.80	1.39	0.606690
	BMI (kg/m^2)	40	44.58	42.73	46.42	44.14	35.15	57.75	40.28	49.06	5.77	0.91	0.821564
Lary-Flex	Age (yrs)	39	38.05	34.35	41.75	35.00	20.00	64.00	30.00	47.00	11.42	1.83	
	Weight (kg)	39	124.90	119.78	130.02	125.00	95.00	160.00	115.00	132.00	15.79	2.53	
	Height (cm)	39	167.31	164.47	170.15	165.00	152.00	190.00	162.00	170.00	8.76	1.40	
	BMI (kg/m^2)	39	44.99	43.28	46.70	43.82	38.75	60.97	40.77	49.08	5.28	0.85	

95% CI: confidence interval; Q1: quartile 1; Q3: quartile 3; SD: standard deviation; SE: standard error.

3. Data Analysis

Our primary endpoint was the time required for successful intubation for each device. The secondary endpoints are evaluation of the efficacy of the study devices in improving glottic visualization and the cardiovascular response to intubations.

Statistical analysis was performed with Statistica 10.0 software (Statsoft, Tulsa, OK, USA). For evaluation of data distribution, the Shapiro-Wilk test was used. The Mann-Whitney U test was used for nonpaired categorical and continuous data analysis (time of intubation). For evaluation of numerical scales a Spearman correlation ratio of rang was used. The Chi square test for independent pairs was used with the Yates correction as required (analysis of failed intubation). Post hoc testing was performed with the Fisher LSD test. Kaplan-Meier curves were drawn and a Log-rank test was performed for group comparison. P values lower than 0.05 were considered statistically significant.

4. Results

Complete data was collected in 40 patients in the Levitan group and 39 patients in the Lary-Flex group. Demographic data are presented in Table 2. Results of evaluation of preintubation conditions are presented in Table 3. There were no statistical differences in the demographic profiles of groups or in the preintubation tests. For evaluation of intubation conditions, there were no statistically significant differences (Table 4). In the Levitan group, the intubation time was

Table 3: Evaluation of preintubation conditions data of studied groups.

Group	Parameter	N	Mean	95% CI		Median	Minimum	Maximum	Q1	Q3	SD	SE	P value Levitan versus Lary-Flex
Levitan	Mallampati scale	40	1.28	1.11	1.44	1.00	1.00	3.00	1.00	1.50	0.51	0.08	0.960896
	Thyromental distance	40	6.78	6.57	7.00	6.70	6.0	8.10	6.25	7.30	0.67	0.11	0.705785
Lary-Flex	Mallampati scale	39	1.28	1.12	1.45	1.00	1.00	3.00	1.00	2.00	0.51	0.08	
	Thyromental distance	39	6.84	6.64	7.04	6.90	6.0	8.00	6.30	7.30	0.61	0.10	

95% CI: confidence interval; Q1: quartile 1; Q3: quartile 3; SD: standard deviation; SE: standard error.

Table 4: Evaluation of intubation conditions data of studied groups.

Group	Parameter	N	Mean	95% CI		Median	Minimum	Maximum	Q1	Q3	SD	SE	P value Levitan versus Lary-Flex
Levitan	Intubation time	40	8.57	7.72	9.43	8.00	5.00	18.00	7.00	9.50	2.66	0.42	*0.000000*
	Number of attempts	40	1.08	0.99	1.16	1.00	1.00	2.00	1.00	1.00	0.27	0.04	0.705785
	C/L 1	40	1.75	1.43	2.07	1.00	1.00	4.00	1.00	2.00	1.01	0.16	0.898564
	C/L 2	40	1.00			1.00	1.00	1.00	1.00	1.00	0.00	0.00	1.000000
	K1	40	5.15	4.39	5.91	3.50	3.00	9.00	3.00	7.00	2.38	0.38	0.848359
	K2	40	3.60	3.25	3.95	3.00	3.00	7.00	3.00	4.00	1.08	0.17	0.651942
Lary-Flex	Intubation time	39	5.79	5.40	6.19	6.00	3.00	8.00	5.00	7.00	1.22	0.20	
	Number of attempts	39	1.03	0.97	1.08	1.00	1.00	2.00	1.00	1.00	0.16	0.03	
	C/L I	39	1.72	1.44	2.00	1.00	1.00	4.00	1.00	2.00	0.86	0.14	
	C/L II	39	1.00	—	—	1.00	1.00	1.00	1.00	1.00	0.00	0.00	
	K1	39	4.90	4.19	5.60	4.00	3.00	9.00	3.00	7.00	2.17	0.35	
	K2	39	3.41	3.16	3.66	3.00	3.00	6.00	3.00	4.00	0.79	0.13	

95% CI: confidence interval; Q1: quartile 1; Q3: quartile 3; SD: standard deviation; SE: standard error; C/L 1: evaluation of laryngoscopic view in Cormack-Lehane scale at beginning of intubation: for Levitan group using only laryngoscope, for Lary-Flex group using videolaryngoscope as standard laryngoscope; C/L 2: evaluation of laryngoscopic view using Levitan FPS or looping on monitor of Lary-Flex videolaryngoscope. Intubation conditions were evaluated using Krieg scale K1 in Levitan group using only laryngoscope, in Lary-Flex group using videolaryngoscope as standard laryngoscope and K2 using Levitan FPS and using whole videolaryngoscope set.

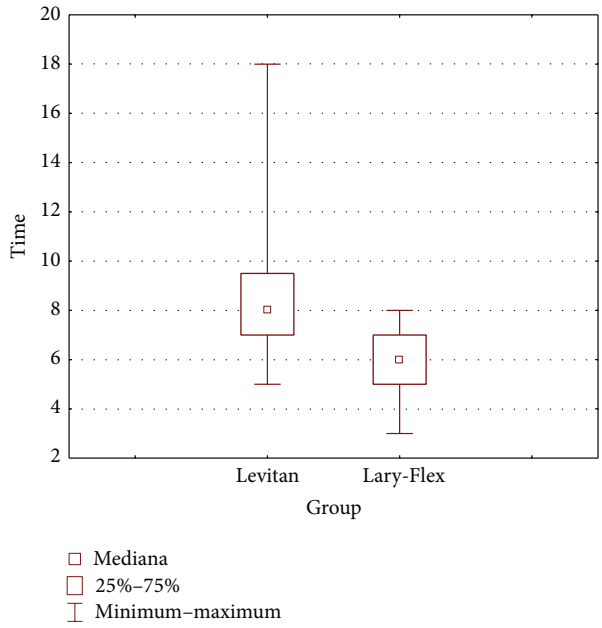

Figure 4: Time for intubation with studied devices (s).

Table 5: Evaluation of participants opinion of potential improvement of intubation conditions.

Group	Improvement of intubation conditions	
	No	Yes
Levitan	45.00%	55.00%
Lary-Flex	48.72%	51.28%

significantly longer but still within acceptable clinical limits—Table 4, Figure 4. Evaluations of the intubation conditions are presented in Figures 5, 6, and 7. In all cases of CL grade > 1 in direct laryngoscopy the study devices improved CL grade to 1. No complications of intubation were observed.

Most of anesthesiologists felt the study devices improved intubation conditions (Table 5). When using the Levitan FPS, the cardiovascular response was significantly larger in comparison to the Lary-Flex videolaryngoscope (Table 6).

5. Discussion

There is a wide range of videolaryngoscopes and other airway devices currently available. Videolaryngoscopes can be

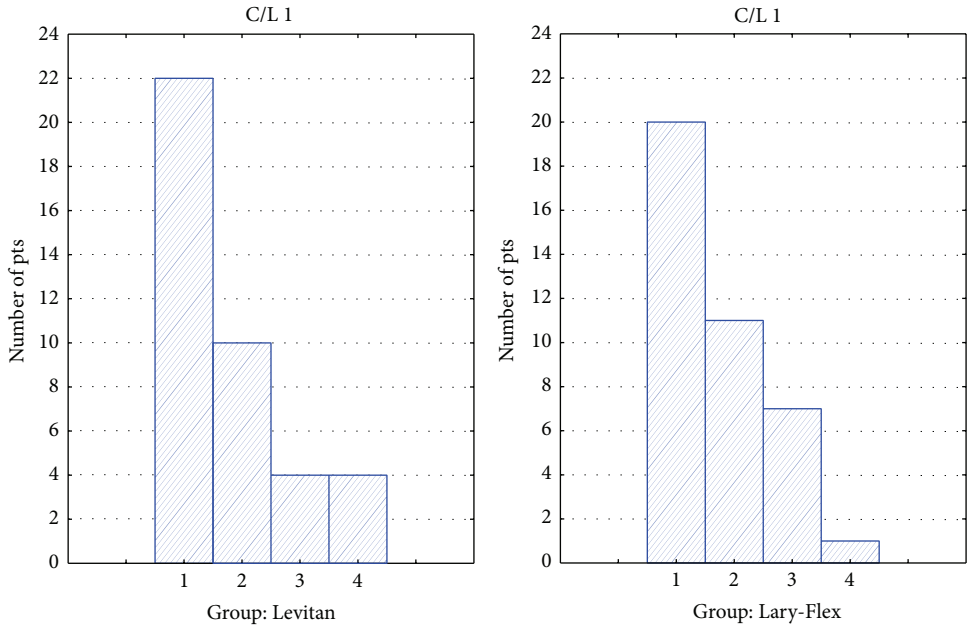

Figure 5: Histogram of evaluation of laryngeal view: Macintosh blade laryngoscope (Levitan group) or Lary-Flex as standard laryngoscope (Lary-Flex group).

Table 6: Cardiovascular response to intubation attempts.

Group	Parameter		N	Mean	95% CI		Median	Minimum	Maximum	Q1	Q3	SD	SE	P value Levitan versus Lary-Flex
Levitan	SPB	T1	40	119.03	114.14	123.91	119.00	94.00	143.00	105.50	130.50	15.29	2.42	0.197238
		T2	40	129.07	124.23	133.92	126.00	108.00	160.00	114.00	143.00	15.15	2.40	*0.000000*
	DBP	T1	40	74.25	70.81	77.69	72.50	50.00	94.00	66.50	80.50	10.76	1.70	*0.007321*
		T2	40	81.03	78.07	83.98	80.00	63.00	96.00	74.00	90.00	9.24	1.46	*0.000000*
	MAP	T1	40	102.88	97.86	107.89	101.00	71.00	132.00	94.00	110.00	15.69	2.48	***0.000004***
		T2	40	88.50	85.05	91.95	88.00	66.00	110.00	81.00	97.00	10.78	1.70	***0.000000***
	HR	T1	40	88.53	83.42	93.63	85.00	54.00	122.00	77.50	96.00	15.95	2.52	*0.000000*
		T2	40	75.88	71.89	79.86	77.50	54.00	105.00	65.00	85.00	12.46	1.97	*0.000029*
Lary-Flex	SBP	T1	39	113.97	106.40	121.55	119.00	73.00	165.00	94.00	130.00	23.38	3.74	
		T2	39	102.51	97.31	107.71	101.00	71.00	143.00	94.00	118.00	16.04	2.57	
	DBP	T1	39	66.05	60.48	71.62	61.00	40.00	98.00	52.00	83.00	17.19	2.75	
		T2	39	58.69	54.68	62.70	58.00	42.00	98.00	50.00	64.00	12.37	1.98	
	MAP	T1	39	81.18	75.51	86.85	78.00	54.00	112.00	66.00	98.00	17.48	2.80	
		T2	39	73.13	68.83	77.42	73.00	52.00	112.00	64.00	78.00	13.25	2.12	
	HR	T1	39	64.41	61.17	67.65	66.00	48.00	82.00	53.00	72.00	9.98	1.60	
		T2	39	63.92	61.26	66.58	66.00	51.00	77.00	55.00	70.00	8.20	1.31	

T1: preintubation (postinduction); T2: postintubation.

divided into subgroups: Macintosh-like blades (e.g., C-Mac, McGrath MAC) and modified blades (e.g., McGrath Series 5, Glidescope). The TruView PCD, which we have used, is a laryngoscope with a modified blade. The glottic view is obtained through the optical view tube incorporated into the blade; a video system can be additionally connected. There are also devices with a special channel for the endotracheal tube, for example, AirTraq, Pentax AWS, and King Vision. Nasotracheal AirTraq intubation, which we used, is modified: it has no channel for the tube. A separate group of airway devices are optical stylets. They combine features of fibroscopes and intubation stylets. The intubation tube should be placed over

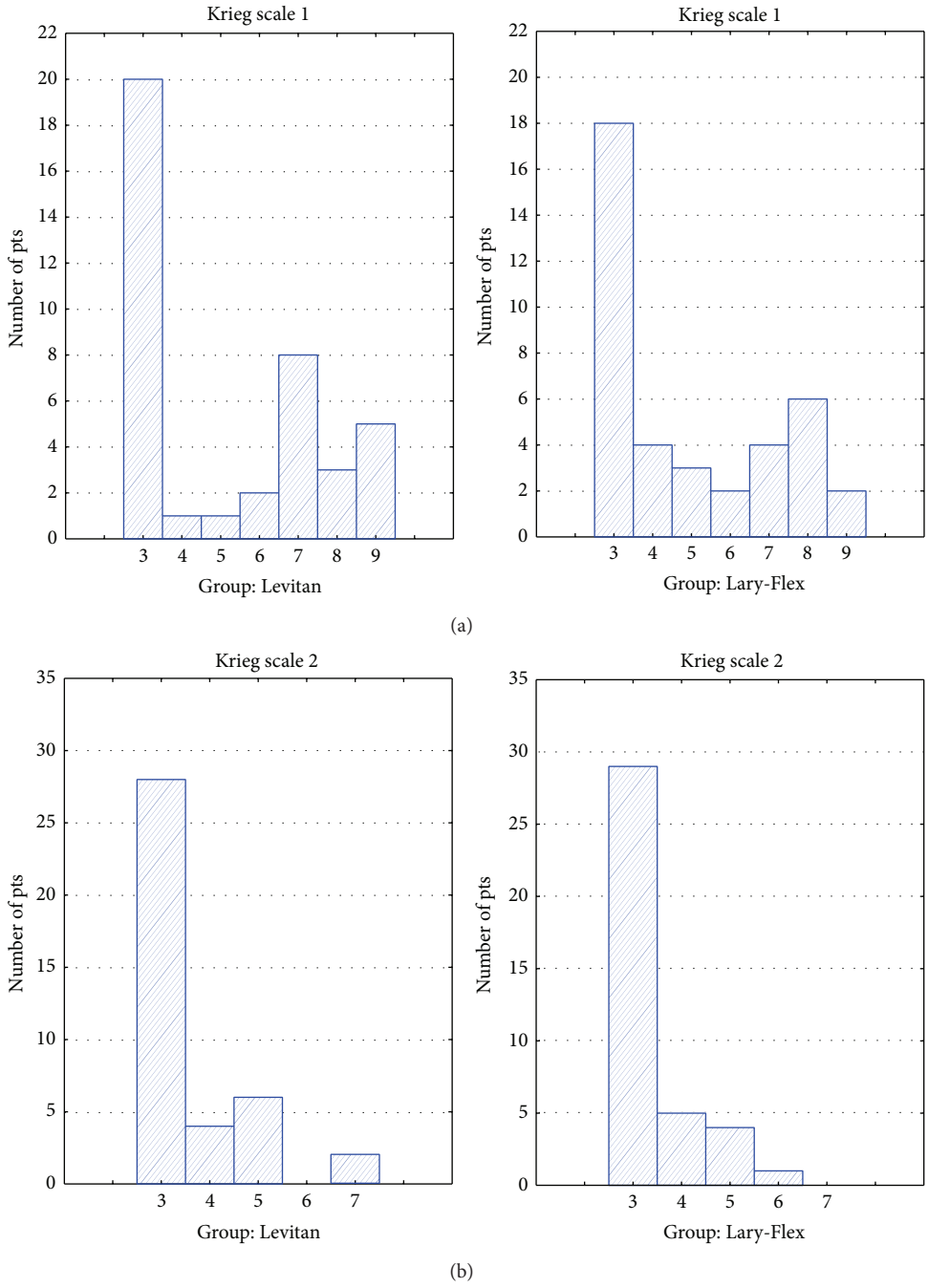

Figure 6: Histograms of evaluation of intubation conditions: Krieg scale 1, conditions using Macintosh blade laryngoscope (Levitan group) or Lary-Flex as standard laryngoscope (Lary-Flex group), Krieg scale 2, conditions using devices.

the optical stylet before using. The operator may use them as intubation stylets together with the laryngoscope. When using rigid optical stylets, the operator can look through the ocular (Bonfils, Levitan FPS) like in a fiberscope and observe the entrance to larynx. This allows for location of entrance to larynx in difficult cases and increases the safety of the procedure. The optical stylets are rigid. Only one of the optical stylets, SensaScope, is a rigid optical stylet with a moving tip similar to fiberscopes.

Each device has its advantages and disadvantages. Videolaryngoscopes are advantageous in that they function very similar to that of standard laryngoscopes. As a result, anesthesiologists can quickly master the skill to effectively employ this device. A possible disadvantage to its use is fogging, which may be resolved in a variety of ways. For example, in the case of the C-Mac, applying antifog solution or for AirTraq the device should be turned on 30 seconds prior to use, to warm up the lens. In the case of the TruView

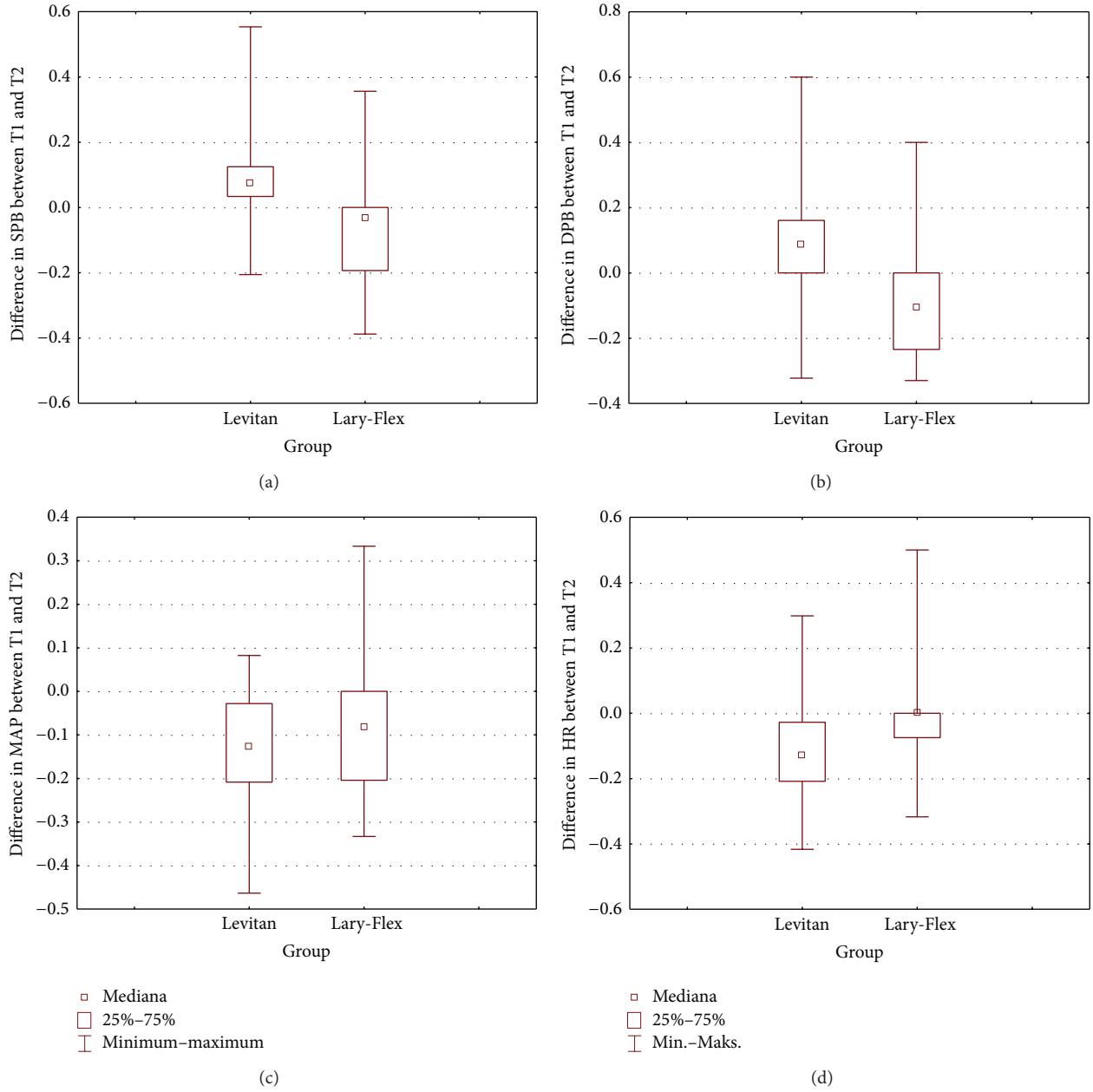

Figure 7: Differences in cardiovascular parameters between time points [%]. T1: preintubation (postinduction), T2: postintubation.

PCD, constant oxygen flow to the lens area prevents fogging and removes secretions from the view. Optical stylets have disadvantages similar to fiberscopes: limited view, possible fogging, and further limitation of view by secretions. The advantage to using optical stylets is that they are similar in use to standard intubation introducers; they are easy to use and requiring minimal training.

The general indications for all devices mentioned above are in situations of both predicted and unexpected difficult intubation. Such devices are becoming more frequently employed in cases of standard patients because they provide optimal prevention of possible intubation injuries in comparison to standard laryngoscopes. In the case of predicted intubation difficulties (like in the case of morbidly obese patients) the fiberscope is preferred; however, the modern airway devices can be a good alternative. For the anesthesiologists who are using the new devices during every day practice they create new opportunities to manage difficult patients in an effective way, including morbidly obese patients [1].

The primary goal was to improve the time required for intubation. As evidenced with use of the Lary-Flex videolaryngoscope, intubation times were slightly improved.

Though intubation conditions were comparable, the cardiovascular response to intubation attempts was smaller while employing the Lary-Flex videolaryngoscope. However, the majority of participants stated that both devices seemed to improve intubation conditions.

The use of videolaryngoscopes in morbidly obese patients not only improves glottic view but also makes intubation efforts easier and less traumatic [14, 15]. Therefore, although obesity is not associated with a higher probability of difficult intubation, endotracheal intubation in morbidly obese patients success requires skill and usually more strength. In our study we confirmed previous reports results that standard Mallampati evaluation cannot predict an increased Cormack-Lehane score in morbidly obese patients [16], and in this group of patients it is justified to use videolaryngoscopes as a standard practice. The Lary-Flex videolaryngoscope and Levitan FPS optical stylet proved to be very good, effective, and easy to use even for anesthesiologists with limited experience using videolaryngoscopes. There is no other study evaluating the Lary-Flex or Levitan FPS in morbidly obese patients. In the study describing the use of V-Mac videolaryngoscope (previous version of C-Mac) in morbidly obese patients, Maassen et al. demonstrate similar results to ours: intubation time of 17 sec. but more intubation efforts (average 1.4) [17]. We evaluated the C-MAC videolaryngoscope (Storz, Germany) in morbidly obese patients and we found that it improved the laryngeal view [9]. In this study and the presented study, all cases of the intubation were successful within the recommended time for intubation attempts, which is especially important in morbidly obese patients, in whom desaturation is faster than that in nonobese patients [18]. Maassen et al. compared three videolaryngoscopes: Storz V-MAC, Glidescope Ranger, and McGrath in MO patients [17]. They concluded that the Storz V-MAC was better than the other devices evaluated for intubation of MO patients. Dhonneur et al. proved that the use of the X-Lite Videolaryngoscope improved intubation conditions in MO [15]. Ndoko et al. evaluated the AirTraq in MO and demonstrated similar results to those concluded within our study; AirTraq is a useful device in this group of patients [19]. We evaluated the AirTraq in morbidly obese patients and found that it improves intubation conditions in such patients [20]. Dhonneur et al. also validate similar results [15, 21]. Andersen et al. compared the Glidescope videolaryngoscope and the standard laryngoscope [22]. Slightly longer intubation times were attained; however, significantly better intubation difficulty scale scores were also achieved with use of the Glidescope. The use of a videolaryngoscope is justified in patients in whom the probability of difficult intubation is increased because of coexisting diabetes mellitus, a common comorbidity in morbidly obese patients [23]. Videolaryngoscopes may be used instead of fibroscopes for awake intubation [24, 25].

The cardiovascular response to videolaryngoscopy is smaller when compared to the use of standard Macintosh laryngoscopes in morbidly obese patients [17]. The cardiovascular response while using the Levitan FPS was not previously evaluated in such patient population. As noted in other studies, Levitan FPS should provoke less of a cardiovascular response comparing to standard laryngoscopy [26]. Some authors compared fiberoptic intubation with the use of Bonfils optical stylets. They concluded that both devices require a similar time for successful orotracheal intubation and cause a similar magnitude of hemodynamic response [27]. As evidenced in our study, the response to intubation using the Levitan FPS device was greater than that of the Lary-Flex videolaryngoscope. This may be justified as the Macintosh laryngoscope was employed while using the Levitan FPS device.

The cardiovascular response to the videolaryngoscopy may be similar to insertion of supraglottic devices in morbidly obese patients [28]. By reducing the stress response, videolaryngoscopes may prove advantageous to the standard laryngoscope in obese patients. Although transitory hypertension and tachycardia are probably of little clinical consequence in healthy individuals, they may be a matter of concern in patients with known, or at risk of, cardiovascular disease such as obese patients [28]. Smaller release of stress hormones may influence the postoperative outcome [28]. The response from the cardiovascular system is smaller for videolaryngoscopes than that with standard laryngoscopy [29]. Although fiberoptic intubation in morbidly obese is still recommended, there is no evidence that this technique is superior to videolaryngoscopy [30]. On the contrary, some studies demonstrate that videolaryngoscopy is good alternative to fiberoptic intubation in morbidly obese patients [30].

Both the Lary-Flex videolaryngoscope and the Levitan FPS optical stylet proved to be very effective for intubation of morbidly obese patients. Therefore, we suggest that videolaryngoscopes and optical stylets should be recommended for routine practice in anesthesia for morbidly obese patients.

6. Conclusion

Both devices, the Lary-Flex videolaryngoscope and the Levitan FPS optical stylet, improve the laryngeal view in morbidly obese patients and allowed for efficient endotracheal intubation. However, the Lary-Flex videolaryngoscope produced less cardiovascular response to endotracheal intubation attempt.

Conflict of Interests

The authors declare that there is no conflict of interests regarding the publication of this paper.

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Clinical Study

The Effect of Sufentanil Administration on Remifentanil-Based Anaesthesia during Laparoscopic Gynaecological Surgery: A Double-Blind Randomized Controlled Trial

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This study assessed the effect of sufentanil administered before conclusion of remifentanil-based anaesthesia on postoperative hyperalgesia and haemodynamic stability in patients undergoing laparoscopic gynaecological surgery. The patients were randomly allocated to a sufentanil administration group (S group) or a normal saline administration group (C group). Anaesthesia was induced and maintained with controlled administration of remifentanil at 10 ng·mL^{-1} and propofol under bispectral index guidance. Once the surgical specimen was procured, sufentanil or normal saline was administered at 0.15 ng·mL^{-1} and maintained until extubation. The haemodynamic status during anaesthetic emergence was evaluated. The pain and postoperative nausea and vomiting (PONV) were assessed for 72 h following postanaesthetic care unit (PACU) discharge. The S group had significantly lower mean systemic arterial blood pressure and heart rate changes between the start of drug administration and extubation. Postoperative pain was significantly lower in the S group until 24 h following PACU discharge. There were no significant differences in PONV incidence and severity 72 h after PACU discharge between the two groups. Sufentanil administration before concluding remifentanil-based anaesthesia improved postoperative hyperalgesia and achieved haemodynamic stability at extubation without delaying recovery or increasing PONV during laparoscopic gynaecological surgery. Clinical trial registration is found at KCT0000785.

1. Introduction

The combination of propofol as a hypnotic agent and remifentanil as an analgesic agent is the most popular regimen for achieving stable haemodynamic and surgical states during total intravenous anaesthesia (TIVA) [1–3]. Generally, the required propofol dose is adjusted to maintain the bispectral index (BIS) between 40 and 60 during general anaesthesia [4], and the required remifentanil dose is adjusted maximally to mitigate the neurohumoral response to surgical stress during TIVA. Remifentanil is rapidly metabolized by unspecific blood and tissue esterases and the metabolites are largely inert [5]. Therefore, a patient administered a high intraoperative remifentanil dose may experience increased postoperative pain requiring additional analgesic agents immediately following remifentanil cessation [6, 7]. Patient anxiety and haemodynamic instability can occur during the postoperative period.

Sufentanil remains metabolically active longer than remifentanil [8], but sufentanil administration for a short duration results in early recovery [9]. Sufentanil administration during emergence from desflurane general anaesthesia reduced the postoperative analgesic requirement without increasing postoperative nausea and vomiting (PONV) [10]. Therefore, we hypothesized that sufentanil administration before anaesthetic conclusion may prevent postoperative hyperalgesia and haemodynamic instability during remifentanil-based anaesthesia. The present study assessed

the effect of sufentanil administered before the conclusion of anaesthesia on postoperative hyperalgesia and haemodynamic parameters during laparoscopic gynaecological surgery under remifentanil-based anaesthesia.

2. Materials and Methods

2.1. Study Population. This prospective, double-blind, and randomised study was approved by the Institutional Review Board (KUH1160057, Institutional Review Board of Konkuk University Medical Centre, Seoul, Republic of Korea) and registered at http://cris.nih.go.kr (KCT0000785). Written informed consent was obtained from all patients. Patients undergoing laparoscopic gynaecological surgery with postoperative intravenous patient controlled analgesia (PCA) were enrolled. The exclusion criteria were as follows: (1) urgent or emergent case, (2) repeat procedure, (3) egg or soybean oil allergy, (4) drug abuse history, (5) current medications for 3 months which could influence postoperative pain and PONV, (6) prolonged QT on preoperative electrocardiography, (7) other concurrent surgeries, (8) surgical duration less than 1 h, (9) hospital discharge within 72 h, and (10) inability to be interviewed. The patients were randomly allocated to the sufentanil group (S group) or normal saline group (C group) using sealed envelopes containing the allocation. Participating anaesthesiologists, surgeons, and nurses were blinded to the study. All data were collected by trained observers who were blinded to the study and did not participate in patient care.

2.2. Anaesthetic Protocol. Preanaesthetic medication was not administered to the patients. Upon arrival to the surgical suite, routine patient monitoring was established, and anaesthesia was induced. The anaesthetic technique was standardized for both groups; lidocaine 0.5 mg·kg^{-1} was administered intravenously to decrease pain induced by propofol. An initial target concentration (effect-site, modified Marsh model with k_{e0} 1.21 min^{-1} [11]) of propofol 4 μg·mL^{-1} and the fixed target concentration (plasma, Minto model [12, 13]) of remifentanil 10 ng·mL^{-1} were administered intravenously using two target controlled infusion (TCI) devices. The target remifentanil concentration of 10 ng·mL^{-1} was achieved 10 min after administration and maintained during anaesthesia. An initial target propofol concentration was titrated with 0.1 μg·mL^{-1} increments to maintain the BIS between 40 and 60. Rocuronium 0.6 mg·kg^{-1} was administered intravenously to induce muscle relaxation after loss of consciousness, guided by peripheral neuromuscular transmission (NMT) monitoring. Endotracheal intubation was performed once the target concentration of remifentanil 10 ng·mL^{-1} was reached and the train-of-four count was 0. Additional rocuronium was administered under peripheral NMT monitoring. Once the surgical specimen was procured, sufentanil (S group) or normal saline (C group) was administered intravenously at a targeted concentration of 0.15 ng·mL^{-1} (plasma, Gepts' model) [9]. A 50 mL syringe containing 5 mL sufentanil (250 mg) and 45 mL normal saline (S group) or only 50 mL normal saline (C group) for TCI was prepared by a registered nurse blinded to the study and not participating in patient care.

The patient was intravenously administered 30 μg phenylephrine (mean systemic arterial blood pressure [MBP] < 60 mmHg and heart rate [HR] > 40 beats·min^{-1}), 4 mg ephedrine (MBP < 60 mmHg and HR < 40 beats·min^{-1}), or atropine (HR < 40 beats·min^{-1}), as needed, to prevent hypotension or bradycardia. Phenylephrine was continuously infused if the MBP < 60 mmHg persisted despite phenylephrine therapy. Nicardipine (0.5 mg) was intravenously administered at a systolic blood pressure > 180 mmHg or diastolic blood pressure > 110 mmHg, and 30 mg esmolol was administered intravenously at MBP > 60 mmHg and HR > 110 beats·min^{-1} during anaesthesia after the target remifentanil concentration was achieved. The remifentanil and propofol TCIs were stopped postoperatively after incision bandaging. Ketorolac (0.5 mg·kg^{-1}) was administered intravenously to control postoperative pain, and an intravenous PCA pump was connected to the patient at surgery conclusion. The PCA regimen consisted of 1,500 μg of fentanyl in normal saline to a total 150 mL volume administered only at basal dose of 0.02 mL·kg^{-1}·h^{-1} without on-demand dose. Residual neuromuscular paralysis was antagonized with intravenous administration of 0.05-mg·kg^{-1} neostigmine and 0.01-mg·kg^{-1} glycopyrrolate under peripheral NMT monitoring. After endotracheal extubation, the administration of sufentanil (S group) or normal saline (C group) was discontinued, and the patient was transferred to the postanaesthetic care unit (PACU).

2.3. Measurements. The MBP, HR, and BIS were measured at sufentanil (S group) or normal saline (C group) initiation (T_s) and after extubation (T_e). The change in MBP (ΔMBP), HR (ΔHR), and BIS (ΔBIS) between T_s and T_e was calculated. The concentration at extubation, total infused amount, and infusion duration of sufentanil (S group) or normal saline (C group) were recorded. Anaesthetic and surgical durations and the emergence time were also recorded. The total infused remifentanil, propofol, phenylephrine, ephedrine, and atropine doses were also recorded.

Postoperative pain was assessed using the visual analogue scale (VAS, ranging from 0 to 100 mm: 0 = no pain and 100 = worst pain imaginable) on PACU arrival ($T1$), 30 min after PACU arrival ($T2$), and at 24 ($T3$), 48 ($T4$), and 72 h after PACU discharge ($T5$). Ketorolac (0.5 mg·kg^{-1}) was administered intravenously as the first-line analgesic on demand. If ketorolac was not effective, then 0.2-mg·kg^{-1} meperidine was administered intravenously as the second-line analgesic on demand.

Postoperative nausea and vomiting (PONV) was assessed on a 3-point ordinal scale (0 = none, 1 = nausea, 2 = retching, and 3 = vomiting) [14] at $T1$ and between $T1$ and $T2$, $T2$ and $T3$, $T3$ and $T4$, and $T4$ and $T5$. PONV severity during $T2$ through $T5$ intervals was evaluated using the Rhodes index [15]. It described the severity of PONV, using a numerical scale from 0 to 32, including subjective (the degree of severity) and objective (with/without nausea, retching, and vomiting and times of nausea, retching, and vomiting)

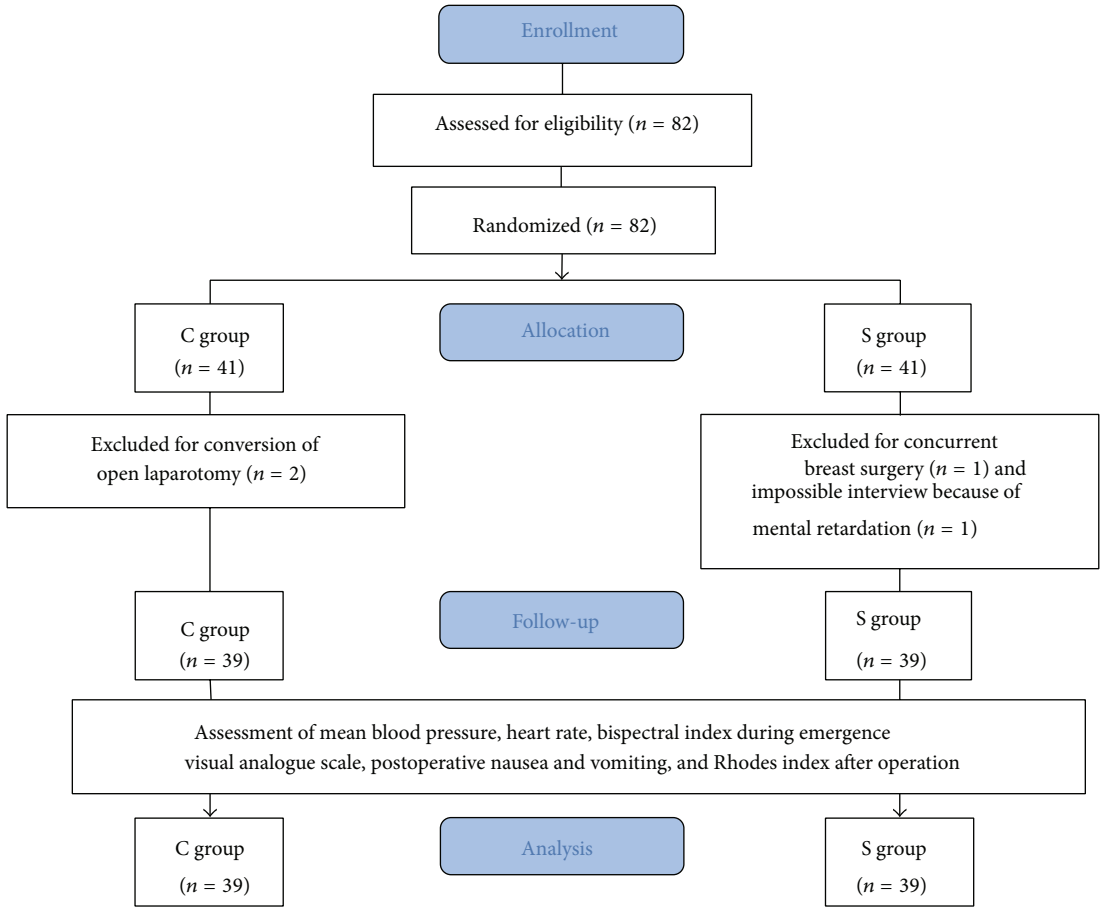

Figure 1: CONSORT flow diagram for the study.

points of PONV. Metoclopramide (10 mg) was administered intravenously as the first-line antiemetic on demand. If metoclopramide was ineffective, then 4 mg ondansetron was administered intravenously as the second-line antiemetic on demand. Dexamethasone (5 mg) intravenously followed as the third-line antiemetic on demand.

2.4. Statistics. Based on a pilot study of 10 patients undergoing gynaecological laparoscopic surgery under the C group regimen, ΔMBP of 31 ± 12 mmHg, ΔHR of 28 ± 10 beats·min^{-1}, and VAS at $T2$ of 51 ± 13 were obtained. The primary outcome was VAS at $T2$, and a minimum 30% VAS decrease between the groups was considered clinically significant. A sample size of 17 was calculated at 0.9 power and 0.05 α value. The secondary outcome was postextubation haemodynamic stability, expressed as ΔMBP and ΔHR. A minimum 30% decrease in ΔMBP and ΔHR between the groups was considered clinically significant. Sample sizes of 39 for ΔMBP and of 33 for ΔHR were calculated at a 0.9 power and a 0.05 α value.

Data were analysed using the Statistical Package for the Social Sciences (SPSS) version 18.0 software. The χ^2 test or Fisher's exact test was used to compare categorical variables. Student's t-test or the Mann-Whitney rank-sum test was used to compare the intergroup differences. The intragroup differences were analysed using the analysis of the variance on ranks for repeated measurements. All data are expressed in terms of number of patients or mean ± standard deviation. A value of $P < 0.05$ was considered statistically significant.

3. Results and Discussion

In total, 82 patients were eligible and 4 patients were excluded: 2 patients in the C group were excluded for conversion to open laparotomy, 1 patient in the S group was receiving concurrent breast surgery, and 1 patient in the S group was unable to participate in the interview because of mental retardation. Thus, 39 patients in each group were included in the final analysis (Figure 1). Patient demographics and recovery times were similar between the two groups (Table 1).

The target plasma concentration of sufentanil (0.15 ng·mL^{-1}) and the target tissue concentration of sufentanil (0.14 ± 0.01 ng·mL^{-1}) at T_e were confirmed in S group. In total, 17 ± 10 μg of sufentanil was administered to the S group. The infused durations of sufentanil in S group and normal saline in C group were 42 ± 24 min and 49 ± 29 min, respectively, with no significant differences noted.

Table 1: Patient demographics.

	C group ($N = 39$)	S group ($N = 39$)	P
Age (years)	40 ± 11	40 ± 13	0.802
Height (cm)	158 ± 6	160 ± 5	0.078
Weight (kg)	58 ± 9	59 ± 9	0.705
Smoking (pack × years)	0	0	—
Hx of motion sickness	1	4	0.358
Hx of PONV	0	0	—
Remifentanil (μg)	3891 ± 1581	3613 ± 976	0.352
Propofol (mg)	791 ± 375	721 ± 288	0.356
Anaesthesia time (min)	170 ± 61	156 ± 37	0.224
Surgery time (min)	137 ± 65	122 ± 36	0.210
Recovery time (min)	14 ± 4	15 ± 10	0.646
Surgical procedures			
Ovarian cystectomy	19	24	0.255
Uterine myomectomy	3	2	0.644
Vaginal hysterectomy	17	13	0.352

Data was expressed as mean ± standard deviation or number of patients.
C group: normal saline group; S group: sufentanil group; Hx: history; PONV: postoperative nausea and vomiting.

Table 2: Haemodynamic parameters and bispectral index.

	T_s	T_e	$T1$	$T_e - T_s$
C group ($N = 39$)				
MBP (mmHg)	79 ± 10	100 ± 13	89 ± 11	20 ± 11
HR (beats·min^{-1})	58 ± 9	83 ± 14	76 ± 13	25 ± 12
BIS	44 ± 4	92 ± 9	—	48 ± 10
Medications				
Phenylephrine (μg)	—	—	—	—
Ephedrine (mg)	—	—	—	—
Atropine (mg)	—	—	—	—
S group ($N = 39$)				
MBP (mmHg)	75 ± 8	86 ± 10*	78 ± 9*	10 ± 9*
HR (beats·min^{-1})	54 ± 7	68 ± 13*	69 ± 12*	14 ± 12*
BIS	46 ± 5	89 ± 8	—	43 ± 9*
Medications				
Phenylephrine (μg)	—	—	—	—
Ephedrine (mg)	—	—	—	—
Atropine (mg)	—	—	—	—

Data is expressed as mean ± standard deviation.
C group: normal saline group; S group: sufentanil group; T_s: initiation of sufentanil (S group) or normal saline (C group) administration; T_e: after extubation; $T1$: on arrival at postanaesthetic care unit.
*$P < 0.05$ compared to the C group.

MBP and HR at T_e in the S group were significantly lower than in the C group (MBP: 86 ± 10 mmHg in S group versus 100 ± 13 mmHg in C group; $P < 0.001$) (HR: 68 ± 13 beats·min^{-1} in S group versus 83 ± 14 beats·min^{-1} in C group; $P < 0.001$) (Table 2). ΔMBP and ΔHR associated with ΔBIS were significantly lower in the S group than the C group (ΔMBP: 10 ± 9 mmHg in S group versus 20 ± 11 mmHg in C group; $P < 0.001$) (ΔHR: 14 ± 12 beats·min^{-1} in S group versus 25 ± 12 beats·min^{-1} in C group; $P < 0.001$) (ΔBIS: 43 ± 9 in S group versus 48 ± 10 in C group; $P = 0.023$) (Figure 2). Phenylephrine, ephedrine, and atropine were not administered during sufentanil or normal saline administrations (Table 2). MBP and HR at $T1$ in the S group were also significantly lower than in the C group (MBP: 78 ± 9 mmHg in S group versus 89 ± 11 mmHg in C group; $P < 0.001$) (HR: 69 ± 12 beats·min^{-1} in S group versus 76 ± 13 beats·min^{-1} in C group; $P = 0.015$) (Table 2).

Postoperative VAS peaked at $T2$ and decreased over time in the two groups. The VAS at $T1$, $T2$, and $T3$ was significantly lower in the S group than in the C group ($T1$: 21±11 in S group versus 48 ± 9 in C group; $P < 0.001$) ($T2$: 27 ± 10 in S group versus 50 ± 8 in C group; $P < 0.001$) ($T3$: 19 ± 8 in S group versus 35 ± 8 in C group; $P < 0.001$) (Table 3). On-demand analgesia was not required at any time in the S group, but 13 patients at $T1$ and 7 patients at $T2$ in the C group required the first-line analgesia, ketorolac (Table 3). Second-line analgesia was not required in either group. PONV incidence and severity and the Rhodes index over time were similar between the groups, with no significant differences noted except at the $T1$ PONV (Table 3). The S group had a significantly lower PONV scale at $T1$. Neither group required the second-line or the third-line antiemetic medications.

The present study showed that sufentanil administration prior to end of remifentanil-based anaesthesia improved postoperative hyperalgesia and haemodynamic stability at extubation without delaying recovery or increasing PONV during laparoscopic gynaecological surgery.

To prevent postoperative hyperalgesia in remifentanil-based anaesthesia, longer acting opioids are commonly administered before anaesthetic emergence [6]. However, this protocol presents problems, such as delayed recovery and postoperative respiratory depression [16, 17]. Haemodynamic instability is frequently encountered during emergence from remifentanil-based anaesthesia [18]. The instability is caused by an increased sympathetic tone combined with the rapid offset of remifentanil effect [19]. As a result, several methods to prevent sympathetic tone increase are employed during emergence from anaesthesia [7, 20]. However, these methods are not capable of blunting sympathetic tone while simultaneously relieving postoperative hyperalgesia [21–23]. Drugs targeting the central nervous system are not robust enough to prevent sympathetic surge, and instead these agents contribute to the delayed recovery and postoperative respiratory depression similar to longer acting opioids [7].

Sufentanil administration prior to anaesthetic conclusion in the present study had a satisfactory effect on both postoperative hyperalgesia and haemodynamic stability. Sufentanil was not administered as single injection but instead continuously with TCI, which meticulously titrates the drug effect compared to single injection and manual infusion [24]. The target sufentanil concentration of 0.15 ng·mL^{-1} was used in the present study. This concentration is the steady-state plasma concentration associated with adequate spontaneous ventilation in 50% of patients [25]. Therefore, the risk of respiratory depression associated with longer acting opioids

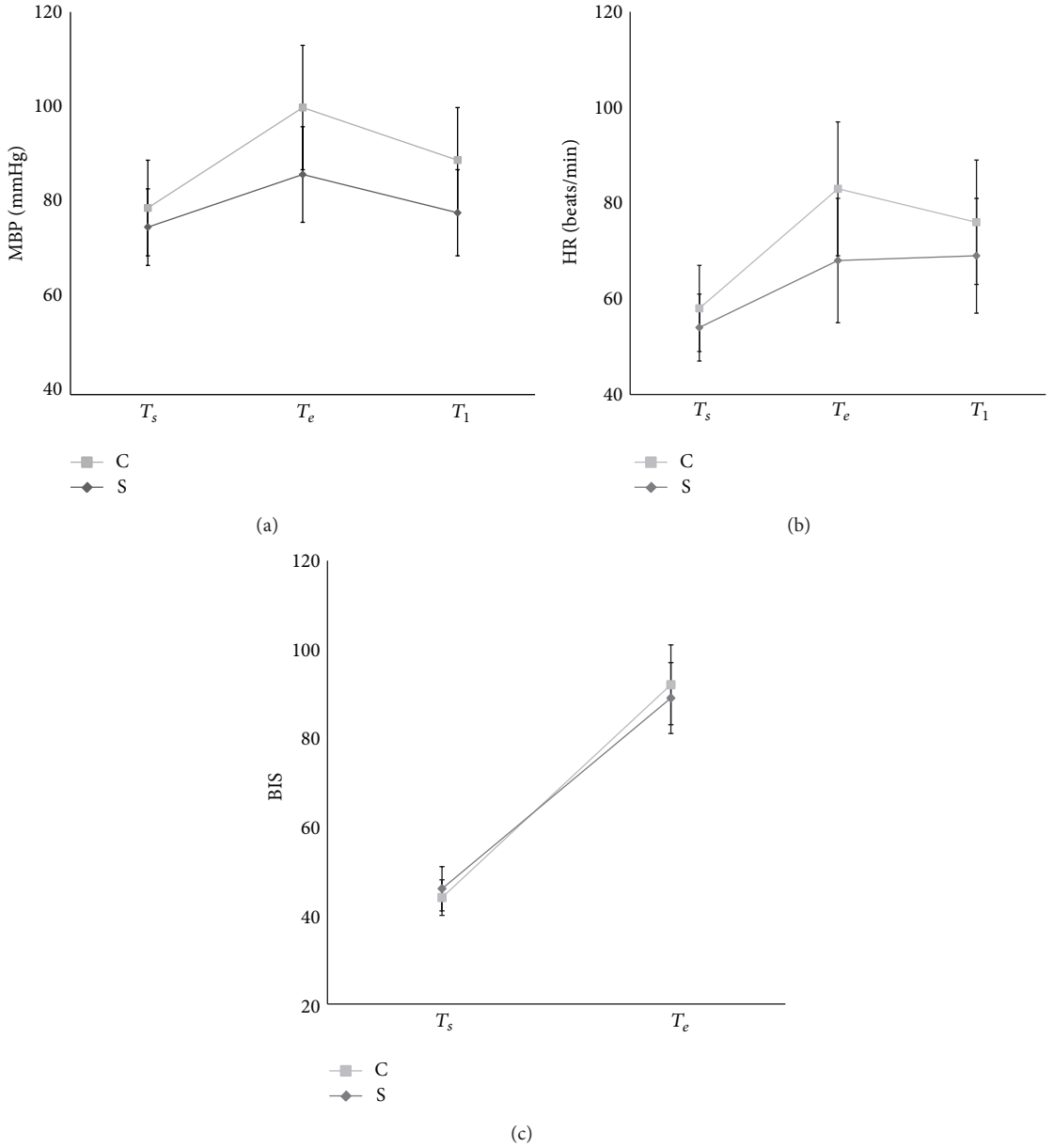

Figure 2: The haemodynamic and neurologic changes during emergence from anaesthesia. (a) Mean systemic blood pressure (MBP), (b) heart rate (HR), and (c) bispectral index (BIS). Abbreviations: T_s, at initiation of sufentanil (S group) or normal saline (C group) administration; T_e, after extubation; and $T1$, on arrival to the postanaesthetic care unit.

or centrally acting drugs was avoided. The context sensitive sufentanil half-life increased as the administration duration increased [26]. Therefore, surgical specimen procurement was the designated sufentanil start time in order to reduce the administration duration while still achieving the target concentration. Sufentanil was administered for 42 ± 24 min in the present study. Not exceeding 1 h of drug administration presumably avoids a delayed recovery.

The present study showed that the postoperative pain improved not only during the PACU stay, but also 24 h after PACU discharge even under a short duration not exceeding 1 h. However, the minimum effective plasma concentration providing postoperative analgesia (MEAC) of sufentanil is 0.025–0.050 ng·mL^{-1} [25]. Therefore, the effect of sufentanil on postoperative analgesia under the present protocol would be maintained for a long time without affecting PACU hospitalization. Bailey et al. showed that sufentanil increased the pain threshold and its duration, irrespective of the dose [27]. The effect of sufentanil on pain threshold was similarly attributed to the improved postoperative pain 24 h after PACU discharge in the present study, although there was no significant difference in use of on-demand analgesia during the $T2$-$T3$ interval in either group. The S group patients did not require additional analgesia at any time. In contrast, the use of the on-demand analgesia peaked in C group 30 min after arrival to PACU; the VAS similarly peaked

Table 3: Postoperative pain based on visual analogue scale (VAS) and postoperative nausea and vomiting (PONV).

	C group ($N = 39$)	S group ($N = 39$)	P
$T1$			
VAS	48 ± 9	21 ± 11	0.000
PONV incidence	6	1	0.108
PONV scale	0.2 ± 0.6	0.0 ± 0.2	0.048
Analgesic	13	0	0.000
Antiemetic	3	0	0.240
$T1$-$T2$			
VAS	50 ± 8	27 ± 10	0.000
PONV incidence	4	5	1.000
PONV scale	0.2 ± 0.5	0.2 ± 0.6	0.712
Analgesic	7	0	0.012
Antiemetic	2	2	1.000
$T2$-$T3$			
VAS	35 ± 8	19 ± 8	0.000
PONV incidence	15	12	0.475
PONV scale	0.6 ± 1.1	0.6 ± 0.9	0.719
Analgesic	3	0	0.240
Antiemetic	3	2	1.000
Rhodes index	3.4 ± 5.3	2.9 ± 5.4	0.613
$T3$-$T4$			
VAS	24 ± 8	24 ± 6	0.743
PONV incidence	3	2	1.000
PONV scale	0.1 ± 0.4	0.1 ± 0.2	0.629
Analgesic	0	0	—
Antiemetic	1	0	1.000
Rhodes index	0.5 ± 2.0	0.2 ± 0.9	0.471
$T4$-$T5$			
VAS	16 ± 6	15 ± 4	0.606
PONV incidence	2	0	0.494
PONV scale	0.1 ± 0.4	0.0 ± 0.0	0.155
Analgesic	0	0	—
Antiemetic	0	0	—
Rhodes index	0.3 ± 1.2	0.00 ± 0.00	0.155

Data was expressed as mean ± standard deviation or number of patients.
C group: normal saline group; S group: sufentanil group; $T1$: on arrival to the postanaesthetic care unit (PACU); $T2$: at 30 min after PACU arrival; $T3$: at 24 h after PACU discharge; $T4$: at 48 h after PACU discharge; $T5$: at 72 h after PACU discharge; PONV assessed on a three- point ordinal scale (0 = none, 1 = nausea, 2 = retching, and 3 = vomiting).

at 30 min in the C group. The postoperative hyperalgesic effect of remifentanil peaked at 30 min after PACU arrival and gradually decreased thereafter; on-demand analgesia use in C group decreased during $T2$-$T3$ and, thus, showed no significant difference between the two groups.

No remarkable PONV differences were observed associated with the sufentanil in the present study, except on arrival to PACU. Potentially, the 0.15-ng·mL^{-1} sufentanil dose was unable to induce PONV, yet it was still capable of blunting the emetic centre. The significantly lower ΔBIS in the S group indicated an incomplete recovery of consciousness, although, ultimately, the BIS did not significantly affect extubation in the two groups. The lightly sedated state could influence emetic centre activity, resulting in the significantly lowered PONV on PACU arrival. Lee et al. reported that sufentanil administrated at 0.2 and 0.3 μg·kg^{-1}·h^{-1} before extubation suppressed cough at extubation and may thus decrease stimulation of the emetic centre [10]. In the present study, cough at extubation was not evaluated. Notably, cough at extubation is associated with increased sympathetic tone. The haemodynamic stability at extubation and on PACU arrival in the present study may potentially decrease the incidence of cough and lessen PONV through the addition of another medication like sufentanil. The total sufentanil dose administered was 22 ± 32 μg, which corresponds to the dosage conducted by Lee et al. As time progressed after PACU arrival, the effect of sufentanil dissipated, and the PCA, which contains fentanyl, produces an identical impact on PONV in both groups.

There was a remaining consideration. A higher sufentanil concentration was associated with improved postoperative hyperalgesia and haemodynamic stability. Derrode et al. reported that TCI of 0.25 ng·mL^{-1} of sufentanil targeting the tissue under Gepts' model was more effective at controlling postoperative pain without compromising recovery in patients undergoing open colorectal surgery, compared to TCI of 1 ng·mL^{-1} of remifentanil targeting the tissue [28]. They also revealed that the mean plasma sufentanil concentration was 0.089 ± 0.038 ng·mL^{-1} targeting a 0.25 ng·mL^{-1} tissue concentration, using Gepts' model [28]. Namely, Gepts' model overestimated sufentanil concentration. The present study also used Gepts' model for sufentanil TCI, and the mean plasma sufentanil concentration was more likely to be lower than the target concentration. Therefore, the present study may have shown better outcomes during anaesthetic emergence and the postoperative period if the higher sufentanil concentration based on Gepts' model had been targeted.

4. Conclusions

Sufentanil administration before concluding remifentanil anaesthesia improved postoperative hyperalgesia and achieved haemodynamic stability at extubation without delaying recovery or increasing PONV during laparoscopic gynaecological surgery.

Conflict of Interests

The authors declare that there is no conflict of interests regarding the publication of this paper.

Acknowledgment

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Research Article

The Cleveland Clinic Experience with Supraclavicular and Popliteal Ambulatory Nerve Catheters

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Continuous peripheral nerve blocks (CPNB) are commonly used for intraoperative and postoperative analgesia. Our study aimed at describing our experience with ambulatory peripheral nerve catheters. After Institutional Review Board approval, records for all patients discharged with supraclavicular or popliteal catheters between January 1, 2009 and December 31, 2011 were reviewed. A licensed practitioner provided verbal and written instructions to the patients prior to discharge. Daily follow-up phone calls were conducted. Patients either removed their catheters at home with real-time simultaneous telephone guidance by a member of the Acute Pain Service or had them removed by the surgeon during a regular office visit. The primary outcome of this analysis was the incidence of complications, categorized as pharmacologic, infectious, or other. The secondary outcome measure was the average daily pain score. Our study included a total of 1059 patients with ambulatory catheters (769 supraclavicular, 290 popliteal). The median infusion duration was 5 days for both groups. Forty-two possible complications were identified: 13 infectious, 23 pharmacologic, and 6 labeled as other. Two patients had retained catheters, 2 had catheter leakage, and 2 had shortness of breath. Our study showed that prolonged use of ambulatory catheters for a median period of 5 days did not lead to an increased incidence of complications.

1. Introduction

Continuous peripheral nerve blocks (CPNB) are often used to provide intraoperative and postoperative analgesia. Effective pain control after painful orthopedic procedures may facilitate earlier patient discharge, improve acute rehabilitation, and increase patient satisfaction. It has been shown that the use of CPNB decreases the use of intravenous (IV) and oral opioids, improves rehabilitation, and decreases length of hospital stay [1–3].

In addition, CPNB were found to provide more potent analgesia than wound catheters and fewer undesirable effects compared to epidural infusion [4]. The development of safe electronic infusion pumps for ambulatory use has improved the feasibility of discharging patients with perineural catheters. It is common practice to leave perineural

catheters *in situ* for a limited period of time (2-3 days) [5, 6]. However, at Cleveland Clinic, ambulatory CPNB are routinely used for a longer period of time with no observed increase in the incidence of complications and with earlier patient mobilization and rehabilitation.

In this retrospective study, we describe our experience with ambulatory CPNB in regard to infection and pharmacological complications.

2. Methods

After Cleveland Clinic Institutional Review Board approval, records for all patients discharged with supraclavicular or popliteal catheters between January 1, 2009 and December 31, 2011 were reviewed. Data collection was performed by investigators from the electronic medical record.

All catheters were inserted using a standard technique. Blocks were performed by a staff anesthesiologist assisting a trainee (resident/fellow). Both physicians, as well as the ancillary personnel (block room nurses and/or technicians), were wearing a new hat and mask for each patient. Both physicians practiced hand wash and removed hand watches, bracelets, and jewelry before putting on sterile gloves. Sterile gowns were not used.

The skin was cleansed with chlorhexidine gluconate in isopropyl alcohol; then a sterile drape was applied and the skin was cleaned for a second time with chlorhexidine. All catheters (Arrow, StimuCath continuous, nerve block procedural kit ASK 05060-cch 19 Ga, 60 cm catheter, insulated needle, 18 g 3.81 inch) were inserted using an in-plane ultrasound technique under strict aseptic conditions with the ultrasound probe covered with a sterile sheath. The catheter was advanced 3–5 cm beyond the needle tip. During supraclavicular catheter insertion, the catheters were placed dorsolateral to the nerve plexus. During popliteal catheter insertion, the catheters were placed next to the nerve with the needle coming from the lateral side of the thigh. The catheter was advanced 3–5 cm beyond the tip of the needle to end within the space between the semitendinosus and semimembranosus muscles medially and biceps femoris muscle laterally.

All catheters were tunneled under the skin, a sterile adhesive and chlorhexidine-impregnated patch were applied around the catheter site, and then the site was covered with clear occlusive dressing. All patients received infusions using the AmbIT pump (Summit Medical Production, Inc., Salt Lake city, UT, USA). We chose this pump as it is technically easy for patients to use and adjust. After catheter placement, an initial bolus dose of 20 mL ropivacaine 0.75% was administered. All patients were evaluated for sensory and motor block prior to surgery. Before discharge, the catheters were connected to AmbIT pumps infusing ropivacaine 0.2% with an 8 mL/hour basal rate and a 12 mL demand dose once per hour. In addition, patients were given a prescription for oxycodone 5 mg every 4 hours with acetaminophen 500 mg (1-2 tablets) every 8 hours; both were to be used as needed for pain for five days. After meeting the discharge criteria, patients with ambulatory catheters were discharged home. Patients needed to have access to a phone to be reached daily, and needed an access to a nearby emergency facility if urgent care was needed.

A licensed practitioner (physician assistant or registered nurse) provided verbal and written discharge instructions to the patients, (Appendix A). The correct use of the infusion pump controls was demonstrated, with repeat demonstration by the patient with family members present. Daily follow-up phone calls were conducted by an Acute Pain Service member, in which they recorded pain scores, signs or symptoms of infection, and pharmacological complications. The rate of infusion was adjusted daily as needed based on the pain score by instructing the patient to reprogram the pump to the desired infusion rate, (Appendix B). Patients either removed their catheters at home with real-time simultaneous telephone guidance by a member of the Acute Pain Service or had them removed by the surgeon during a regular office visit.

On the fifth day, patients were instructed to stop the infusion for 6 hours and then remove the catheter if their pain scores were less than 5 and well tolerated by the patients. If pain was more than or equal to 5 we asked patients to restart their infusions and we did the same every day until the catheter was removed. The primary outcome of this analysis was the incidence of which were categorized as pharmacologic, infectious, or other, for example, retained catheter. The secondary outcome measure was the average daily verbal response pain score.

The patients were compared with basic descriptive statistics by catheter type. Variables of interest included patient demographics, surgery location and type, and infusion duration. Categorical variables are presented as number (percent). Continuous variables are presented as medians with interquartile ranges. R version 2.12.0 (The R Foundation for Statistical Computing, Vienna, Austria).

Any adverse neurologic symptom reported by a patient was listed as a pharmacological complication, regardless of type or severity. Any sign or symptom of infection at the catheter site (erythema, drainage, or swelling) was labeled as an infectious complication. Any other complications such as a retained catheter were labeled as other.

3. Results

A total of 1059 patients with ambulatory catheters (769 supraclavicular, 290 popliteal) were reviewed. The median infusion duration was 5 days for both groups. Table 1 describes patient characteristics and results.

Forty-two complications were identified: 13 were infectious (11 in the supraclavicular group and 2 in the popliteal group), 23 were pharmacologic (22 in the supraclavicular group and 1 in the popliteal group), and 6 were labeled as other. Tables 2, 3, and 4 describe these patients. Two patients had retained catheters which were removed surgically; these were looped around the nerve without actual knotting. Two patients had catheter leakage and two had shortness of breath (one due to pneumonia and the other due to pulmonary embolism and myocardial infarction).

Table 1: Supraclavicular and popliteal catheters.

Catheter type	Surgery site	Procedure	Age (y)	Sex	Duration (days)	Average pain score[†]	Infection	Pharmacologic complication	Other complications
Supraclavicular $N = 769$	Shoulder 498 Elbow 63 Arm 87 Wrist 88 Hand 33	Arthroplasty[*] 257 ORIF 128 Arthroscopy 148 Rotator cuff 87 Tendon repair 19 Other[‡] 130	57 [47, 66]	M 410 F 359	5 [4, 6]	2 [1, 4]	11 (1.4%)	22 (2.9%)	6 (0.8%)
Popliteal $N = 290$	Leg 16 Ankle 198 Foot 76	Arthrodesis 138 ORIF 69 Osteotomy 32 Arthroplasty 11 Other[§] 40	53 [41, 63]	M 103 F 187	5 [4, 7]	2 [1, 3]	2 (0.7%) Total: 1.2%	1 (0.3%) Total: 2.2%	0 (0%) Total: 0.6%

M: male; F: female.
Categorical variables are presented as number of patients.
Continuous variables are presented as median (interquartile range).
[*] "Arthroplasty" includes total and hemiarthroplasty.
[†] "Average pain score" is the time average of daily verbal pain scores (0–10) at telephone contact.
[‡] "Other" ($N < 10$ each) includes closed reduction, external fixation, exploration, debridement, hardware removal, nerve transposition, osteotomy, and arthrodesis.
[§] "Other" ($N < 10$ each) includes incision and drainage, Achilles' tendon repair, and toe amputation.
ORIF: open reduction and internal fixation.

Table 2: Infectious complications.

Age	Sex	Catheter	Duration (days)	Symptoms	Treatment	Comorbidities
42	F	Popliteal	4	Swelling and drainage	Resolved with catheter removal	Thigh abscess
61	F	SC	2	Redness and swelling	Resolved with catheter removal	Hyperlipidemia
52	M	SC	13	Redness and tenderness	Instructed to remove the catheter and see his surgeon, symptoms resolved with no intervention	Hypertension, DM
76	F	SC	4	Redness and swelling	Resolved with catheter removal	Steroid treatment
43	F	SC	2	Redness and swelling	Resolved with catheter removal	Hypertension, hyperlipidemia
35	F	SC	4	Redness and swelling	Resolved with catheter removal	Anemia
38	M	SC	3	Blisters underneath the dressing, redness at the insertion site	Catheter removed in ED, symptoms were resolved within 2 days	None
46	M	SC	5	Redness and tenderness	Resolved with catheter removal	Hypertension, DM, seizures
56	M	SC	7	Redness, swelling, and tenderness	Resolved with catheter removal	None
63	F	SC	3	Redness and purulent discharge	Removed in ED, one dose of IV daptomycin, and oral linezolid	Gastritis, irritable bowel syndrome
60	F	Sc	5	Blisters underneath the dressing and redness	Resolved with catheter removal	None
45	F	Popliteal	6	Redness and tenderness	Resolved with catheter removal	Hypertension, DM
63	M	SC	4	Redness, swelling at the site, nodule 1 inch from the site	CT Of the neck in ED showed no fluid collection, no antibiotics, symptoms resolved within few days	CRPS, hypertension, chronic renal disease, seizures,

SC: supraclavicular catheter; COPD: chronic obstructive pulmonary disease; DM: diabetes mellitus; CT: computerized tomography; CRPS: complex regional pain syndrome; ED: emergency department.

All infections were superficial, presenting as redness and tenderness at the catheter site. In all cases, patients were instructed to remove the catheter. In only one case did the patient require antibiotics; the remainder of the infections resolved without any intervention other than catheter removal.

Pharmacological complications consisted of ringing in the ears, ipsilateral numbness, hoarseness, and significant ptosis. All pharmacological complications resolved after discontinuing the infusion for 2-3 hours or removing the catheter without any sequelae. Most of the pharmacological complications presented in patients with supraclavicular catheters.

The time-weighted average for daily verbal pain scores (0–10) at the time of telephone contact for patients with supraclavicular or popliteal catheters was 2, showing overall satisfactory postoperative pain control.

4. Discussion

Expanded use of regional anesthesia has increased patients' benefit in terms of better control of intraoperative and postoperative pain, increased patient satisfaction, decreased postoperative nausea and vomiting, and early mobilization and rehabilitation.

One of the major concerns regarding the use of CPNB has been the potential for complications, such as catheter site infection, nerve injury, and local anesthetic toxicity. A recent meta-analysis evaluating 19 studies showed that major complications were rare. The most frequent minor complication attributable to peripheral nerve block was excessive motor block [2]. The most common technical difficulties have been related to pump malfunction, catheter misplacement, displacement, obstruction, and catheter migration [2, 3, 6].

The frequency of infection associated with peripheral nerve catheters remains poorly defined. Recent studies have shown that between 23 and 57% of peripheral nerve catheters become colonized, but only 0–3% result in localized infection and less than 1% result in serious infections [7]. The 1.2% infection rate in our study is consistent with the reported rates, although the infusion durations were considerably longer. Severe infectious complications reported in the literature include psoas abscess complicating continuous femoral nerve blocks [8, 9], axillary abscess and necrotizing fasciitis after single shot and continuous axillary nerve blocks [10, 11], and thigh and interscalene abscesses after continuous popliteal, sciatic, and interscalene nerve blocks, respectively [12, 13]. The American Society for Regional Anesthesia and Pain Medicine (ASRA) guidelines highlight the importance of asepsis in regional anesthesia procedures, mainly during needle and catheter insertion, specifically hand washing,

Table 3: Pharmacological complications.

Age	Sex	Catheter	Duration (day)	Symptoms	Treatment	Comorbidities
23	F	Popliteal	4	Ringing in the ears with the initial injection	Resolved completely with no intervention	None
22	F	SC	5	Ipsilateral ptosis	Resolved with holding the infusion for 2 hours	None
73	M	SC	2	Hoarseness	Resolved after catheter removal	Hypertension
48	M	SC	7	Ipsilateral ptosis	Resolved with pump off, returned with infusion, resolved with catheter removal	Hypothyroidism
72	F	SC	7	Numbness of ipsilateral hand	Resolved with catheter removal	None
51	M	SC	3	Ringing in the ears, started at home	Instructed to hold the infusion, but the ringing persists, instructed to remove the catheter, and it was resolved completely	Psoriasis
51	M	SC	5	Hoarseness, ipsilateral numbness, and weakness of the hand	Improved with holding the infusion, resolved with catheter removal	Obesity, DM, smoking
38	F	SC	4	Ipsilateral ptosis	Resolved with catheter removal	Hypothyroidism, smoking
29	M	SC	3	Ipsilateral ptosis and fingers tingling	Resolved with catheter removal	Hyperlipidemia
45	M	SC	4	Ringing and numbness in ipsilateral ear	Resolved with holding the infusion	None
75	F	SC	8	Ipsilateral ptosis and facial hyperemia	Resolved with decreasing the concentration to 0.1% ropivacaine	Rheumatoid arthritis, hypertension, colon cancer, and breast cancer
45	M	SC	3	Ipsilateral ptosis	Improved with holding the infusion, resolved with catheter removal	Obstructive sleep apnea and coronary artery disease
65	M	SC	5	Ipsilateral numbness of the face	Improved with holding the infusion, resolved with catheter removal	Hypertension, gout
38	M	SC	3	Tingling and numbness of ipsilateral fingers	Improved with holding the infusion, resolved with catheter removal	None
42	F	SC	4	Ipsilateral ptosis, stuffy nose, and metallic taste in mouth	Improved with holding the infusion, resolved with catheter removal	None
43	M	SC	4	Ipsilateral ptosis	Improved with holding the infusion, resolved with catheter removal	Osteoarthritis
56	M	SC	7	Weakness and numbness of ipsilateral hand	Gradually improved, resolved with catheter removal	None
65	F	SC	6	Hoarseness	Resolved with catheter removal	Hypertension, anxiety
49	F	SC	5	Hoarseness	Resolved with catheter removal	None
60	F	Sc	5	Hoarseness, ipsilateral ptosis	Improved with holding the infusion, resolved with catheter removal	Anxiety, hypothyroidism
56	F	SC	3	Numbness of ipsilateral fingers	Resolved with catheter removal	Obesity, hypertension, obstructive sleep apnea, and DM
45	F	SC	6	Ipsilateral ptosis and numbness of fingers	Resolved with catheter removal	None
39	F	SC	5	Ipsilateral ptosis	Resolved with catheter removal	Anxiety

the use of protective barriers (mask, gloves, gowns, and drapes) and chlorhexidine-containing skin disinfectants [14]. Guidelines for practice improvement must be built according to specific actual risk applied to each procedure and certainly cannot be extrapolated without some restrictions. CPNB are increasing in popularity, and the incidence of infections associated with CPNB is rare. Pharmacological complications (including neurological symptoms) associated with CPNB are rare. A review of the literature showed that the incidence of neurological symptoms 6 months after the block is 0.6%,

Table 4: Other complications.

Age	Sex	Catheter	Duration (days)	Symptoms	Treatment	Comorbidities
30	F	SC	3	Retained catheter	Removed in ED by surgical extraction at bed side	Depression
62	M	SC	6	Retained catheter	Removed in ED by slight traction with no complication	Coronary artery disease (CAD)
68	F	SC	5	Small amount clear leakage at catheter insertion site	Resolved with reinforced dressing	Osteoarthritis, hypertension
57	M	SC	4	Leakage from catheter tubing	Catheter found to be disconnected at the hub, in ED catheter cleaned with chlorhexidine, cut with sterile scissors, sterile hub applied	Hypertension
70	M	SC	10	Shortness of breath (SOB)	Patient advised to turn off the pump and to go to hospital, chest X-ray showed pneumonia, started on antibiotics, catheter removed	CAD, hypertension
62	F	SC	3	SOB, dizziness, and sweating	Patient advised to turn off the pump and go to the emergency department. Found to have myocardial infarction and pulmonary embolism. Catheter removed. Subsequently discharged home	Hypertension, DM

with most of the symptoms due to causes unrelated to the block [15]. Capdevila et al. [9] reported an incidence of 6.6% in adult population and Ganesh et al. [5] reported an incidence of 1.6%. In the study by Ganesh et al., 108 children were discharged home with ambulatory catheters; the authors reported prolonged numbness (>24 hours) to be the most common complication noticed and it happened in 3 patients [5]. They also reported that numbness resolved spontaneously without any consequences [5]. In our study the incidence of pharmacological complications including neurological complications was 2.2% (2.9% in the supraclavicular group and 0.3% in the popliteal group); most of them were excessive numbness of the blocked limb and all resolved within 24 hours without any residual deficit. The low incidence of pharmacological complications in our study and their short duration may be due to the use of ultrasound in placing our catheters and confirming that the medications are infusing around the nerve and not intraneurally. Two patients had retained catheters which were removed surgically and they found to be looped around the nerve without actual knotting. There were no specific difficulties with the insertion of these two catheters which were threaded the usual 5 cm beyond the tip of the needle. Both catheters were successfully removed by surgical exploration with no complications after radiological localization of the catheters. Knotting of peripheral nerve catheters is rare, occurring in only 0.13% of patients in a retrospective review [16], but it represents the most reported cause for catheter retention in the literature.

A review of the literature shows few cases describing difficulty in removing peripheral nerve catheters mostly secondary to knotting or excessive advancement under the skin, as previous investigators have demonstrated a relationship between length of catheter advancement and subsequent knotting [17]. Considering the multiple catheter knots reported with insertion >5 cm, and the lack of data suggesting insertion lengths >5 cm is beneficial, recommending a maximal insertion of 5 cm seems warranted [4]. Patients with new onset shortness of breath should go to the emergency department as this may be due to coincidental comorbidities in rare occasions, which if not discovered and treated in a timely fashion would be life threatening. Shortness of breath was present in 2 of our patients who had supraclavicular catheters. Both patients were instructed to go to the emergency department. The first was found to have pneumonia and the second was found to have a myocardial infarction and pulmonary embolism. Two other patients had leakage from the catheter port and this was resolved by tightening the connection between the catheter port and the tubing which was performed by a physician in the emergency department.

Despite the rise in popularity of continuous regional techniques for ambulatory surgery, little has been studied regarding patient perception of the technique. Retrospective surveys have shown that patients are generally satisfied with ambulatory perineural infusions including the removal of catheters themselves [18].

5. Conclusion

The results of our study demonstrate that the prolonged use of ambulatory catheters for a period up to 5 days did not lead to an increased incidence of complications as compared to other studies. Our main complications were minor infections and pharmacological symptoms, which resolved with catheter removal and without the need for additional medical intervention. Patients who presented to the emergency department with shortness of breath had other underlying comorbidities such as myocardial infarction and

pulmonary embolism. Vigilance in dealing with patients with ambulatory catheters is crucial to prevent complications.

Appendices

A. AmbIT Pump (discharge instructions)

A.1. Home Going Instructions. Your surgeon and anesthesiology pain management team have determined that a continuous peripheral nerve block is an option for pain management following your surgical procedure. This information is provided for you regarding the outpatient management of the AmbIT pump.

(1) The peripheral nerve block catheter and infusion pump are intended to help reduce your postoperative pain. Not all surgical pain may be relieved by this method of pain control. Therefore, you will likely need oral pain medication prescribed by your surgeon. Please carefully follow the directions for these oral pain medications.

(2) The local anesthetic medication infusing via the AmbIT pump will produce some degree of numbness in the intended surgical area supplied by those nerves. Due to this numbness it is imperative that you remain protective of your surgical limb from heat, pressure, chemicals, or other objects to avoid injury.

(3) You will likely have some degree of muscle weakness in your arm, hand, leg, or foot from the effect of the local anesthetic. Do not support yourself or bear weight on the arm, hand, leg, or foot while the local anesthetic nerve block is infusing.

(4) There are no narcotics in the solution.

(5) This medication will not interfere with any medications you are currently taking. It will also not interfere with any pain medications you have ordered.

(6) The pump does not require height for infusion as opposed to an IV infusion. The solution and AmbIT pump are placed in a fanny pack for your convenience.

(7) Please note that it is important to keep the dressing over the catheter clean and dry. Do not change the dressing. NO SHOWERS.

A.1.1. How to Use the Pump

(1) This pump is disposable and is to be thrown out. It is not reusable.

(2) Left over solution can be disposed of down the sink.

(3) The AmbIT pump runs on 2 AA batteries. New batteries have been placed in the pump.

(4) The AmbIT pump makes a noise while it is infusing, a type of "grinding noise." It will make this noise about every 20–30 seconds while the pump is on.

(5) When you give yourself a bolus dose the AmbIT pump will make a loud continuous grinding noise for about 10 min. This is normal, when the bolus dose is complete the noise will stop.

(6) The AmbIT pump has already been preset with rates.

Basal Rate. This is the continuous rate of the medication per hour.

Bolus Dose. This is for the moment when you need an extra dose of the anesthetic medication. You can give yourself a bolus dose every hour if needed. If you do not need the extra dose there is no need to press the bolus dose button. You cannot overdose yourself; the pump will only give you 1 bolus dose an hour.

(7) This is the Run/Pause button.

(8) This is the bolus dose button.

(9) When the green light is blinking on the bolus dose button it means that the AmbIT pump is on and working.

(10) The screen on the pump reads with a decimal point; it will look like this 136.5 mL. That number continues to count up as the solution infuses. It is designed to turn off when the number reaches 1000.0 mL.

A.1.2. Taking Out the Catheter. Before removing the catheter, make sure that the AmbIT pump has been off for 6–8 hours. We want all of the numbness to be gone and normal sensation returned. If normal sensation has not returned please call the Acute Pain Service.

(1) Wash your hands.

(2) Remove all of the tape.

(3) Gently pull on the catheter; it is in about 5-6 inches. It should come out easily.

(4) If there is resistance or you cannot pull the catheter out, cover the site back up with the provided Tegaderm and call the Acute Pain Service.

(5) After catheter removal, the site may bleed a small amount; this is normal. You may hold pressure over the catheter site for 5–10 minutes and then apply a band aid to the area. The band aid may be removed later in the day.

(6) Notify the Acute Pain Service for any pain, redness, continued bleeding, or drainage from the catheter insertion site and also notify for persistent numbness or weakness in the arm, hand, leg, or foot following the catheter removal.

A.1.3. When to Call the Acute Pain Service. Please contact the Acute Pain Service if you have any questions or notice the following symptoms during or following the nerve block infusion.

(1) Increase in pain.

(2) Redness, tenderness, swelling, or drainage at the nerve block catheter insertion site.

(3) Lightheadedness, dizziness, or sedation.

(4) Blurred vision.

(5) Ringing in your ears, metallic taste in your mouth, numbness, or tingling around your mouth.

(6) Any shortness of breath.

(7) Difficulty in swallowing.

(8) Drowsiness.

(9) Confusion.

(10) Any discoloration (redness, bluish color changes) of the hand, fingers, foot, or toes.

A.2. Contact Information

A.2.1. Acute Pain Service

(1) Acute Pain Service number: (number was provided here).

If no response call:

(2) Consultant: (number is provided here).

If no response call:

(3) The Cleveland Clinic Foundation operator at (number was provided here) and ask for consultant pager (number was provided here).

A.2.2. Trouble Shooting the Pump

(1) If the pump shows *MA* on the screen try replacing the batteries, if that does not work call the Acute Pain Service.

(2) If the pump shows *OCL*, there is a kink somewhere in the tubing. Make sure that the tubing clamps are open and moving freely. Also ensure that you are not lying or sitting on the tubing.

B. Daily Phone Encounter

B.1. Supraclavicular Catheter Documentation following Phone Call

Day of surgery:

Type of surgery:

Catheter site:

Solution:

Rate of infusion:

Called and talked to patient, states pain level is:

Patient states the catheter dressing is (intact or specify if otherwise) and denies: (redness, fever, draining, edema, pain, or specify if otherwise).

Patient denies metallic taste in mouth, ringing in ears, dizziness, shortness of breath, hoarseness of voice, or specify if otherwise.

Patient is able to move fingers: Yes or No.

Comments. Patient is satisfied with pain control, will continue with pump, or specify if otherwise.

B.2. Popliteal (Sciatic) Catheter Documentation following Phone Call

Day of surgery:

Type of surgery:

Catheter site:

Solution:

Rate of infusion:

Called and talked to patient, states pain level is:

Patient states the catheter dressing is (intact or specify if otherwise) and denies: (redness, fever, draining, edema, pain or specify if otherwise).

Patient denies metallic taste in mouth, ringing in ears, dizziness, shortness of breath, hoarseness of voice, or specify if otherwise.

Patient is able to move toes: Yes or No.

Comments. Patient is satisfied with pain control, will continue with pump, or specify if otherwise.

Conflict of Interests

The authors declare that there is no conflict of interests regarding the publication of this paper.

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Clinical Study

Postoperative Pharyngolaryngeal Adverse Events with Laryngeal Mask Airway (LMA Supreme) in Laparoscopic Surgical Procedures with Cuff Pressure Limiting 25 cmH_2O: Prospective, Blind, and Randomised Study

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To reduce the incidence of postoperative pharyngolaryngeal adverse events, laryngeal mask airway (LMA) manufacturers recommend maximum cuff pressures not exceeding 60 cmH_2O. We performed a prospective randomised study, comparing efficacy and adverse events among patients undergoing laparoscopic surgical procedures who were allocated randomly into low (limiting 25 cmH_2O, L group) and high (at 60 cmH_2O, H group) LMA cuff pressure groups with LMA Supreme. Postoperative pharyngolaryngeal adverse events were evaluated at discharge from postanaesthetic care unit (PACU) (postoperative day 1, POD 1) and 24 hours after discharge from PACU (postoperative day 2, POD 2). All patients were well tolerated with LMA without ventilation failure. Before pneumoperitoneum, cuff volume and pressure and oropharyngeal leak pressure (OLP) showed significant differences. Postoperative sore throat at POD 2 (3 versus 12 patients) and postoperative dysphagia at POD 1 and POD 2 (0 versus 4 patients at POD 1; 0 versus 4 patients at POD 2) were significantly lower in L group, compared with H group. In conclusion, LMA with cuff pressure limiting 25 cmH_2O allowed both efficacy of airway management and lower incidence of postoperative adverse events in laparoscopic surgical procedures. This clinical trial is registered with KCT0000334.

1. Introduction

The cuff inflation of endotracheal tube (ETT) is essential to achieve a seal between ETT and tracheal wall. It makes no air leak at airway pressure required for positive pressure ventilation and lung protection from aspiration. The ETT cuff pressure is recommended as below 25–35 cmH_2O to prevent the reduction of perfusion pressure in airway mucosa [1]. A higher cuff pressure in laryngeal mask airway (LMA) is permitted since the device is not located in trachea, surrounded by cartilages. The LMA Supreme (Intavent Orthofix, Maidenhead, UK) cuff pressure is recommended as below 60 cmH_2O by the manufacturer [2]. However, Zhang et al. showed that LMA Supreme cuff pressure of 80 cmH_2O was not associated with a greater incidence of postoperative pharyngolaryngeal adverse events, compared with 40 or 60 cmH_2O [3]. In clinical practices, the cuff inflation of LMA is performed by single or multiple injections with 20–50 mL syringes, inflated with air, to achieve a tight seal and the LMA cuff pressure frequently exceeds 60 cmH_2O [4]. However, several studies have reported that the reduction of cuff pressure of LMA resulted in fewer pharyngolaryngeal complications [5–7]. Brimacombe et al. also reported that small inflated cuff volume of LMA showed lower incidence of sore throat and dysphagia, comparing with high inflated cuff volume [8]. However, the studies have not been performed with LMA Supreme.

Therefore, we hypothesized that the LMA cuff pressure limiting 25 cmH_2O could reduce the postoperative pharyngolaryngeal adverse events, compared with 60 cmH_2O by the

manufacturer, using LMA Supreme. The study was designed to compare the postoperative pharyngolaryngeal adverse events between the LMA cuff pressure limiting 25 cmH_2O (L group) and at 60 cmH_2O (H group). We also investigated the safety and efficacy of cuff pressure limiting 25 cmH_2O in laparoscopic surgical procedures.

2. Materials and Methods

The study was approved by the Institutional Review Board (KUH1160036 granted by the Institutional Review Board of Konkuk University Medical Center, Seoul, Korea) and registered at http://cris.nih.go.kr/cris KCT0000334. Written informed consents were obtained from the patients and the study was conducted in a prospective, blind, and randomised fashion.

2.1. Study Population. Patients undergoing laparoscopic surgical procedures were enrolled. Patients were excluded if the following criteria were present: (1) neurological or psychiatric disorders, (2) vocal cord paralysis, (3) recent history of respiratory infection (within 1 month), and (4) allergy to egg or soybean oil because of risk of allergy to propofol. The patients were randomly allocated before anaesthesia induction into either L group or H group by sealed envelope containing the group assignment.

2.2. Anaesthesia Technique. The anaesthesia technique was standardised. The patient arrived at the operating room without premedication. After establishing routine patient monitoring, anaesthesia was induced by an attending anaesthesiologist who was blind to the study. The following anaesthesia protocol was requested: lidocaine 0.5 mg/kg was administered to decrease pain from propofol injection, followed by intravenous propofol 2 mg/kg for anaesthesia induction and a target plasma concentration of remifentanil of 5 ng/mL, with target-controlled infusion device (Orchestra Base Primea, Fresenius Vial, Brézins, France), according to the Minto model [9]. The remifentanil of 5 ng/mL was maintained until the end of surgery. Rocuronium 0.6 mg/kg was administered for muscle relaxation after onset of deep sedation under the guidance of peripheral neuromuscular transmission (NMT) monitoring. The LMA insertion was performed at train-of-four count of 0. The cuff of the LMA was completely deflated prior to insertion and its dorsal surface was lubricated with jelly. LMA size was determined by patient body weight in accordance with the manufacturer guideline: <50 kg, size 3; 50–70 kg, size 4; 70–100 kg, size 5. The LMA cuff was inflated with air using a 50-mL syringe and the cuff pressure was adjusted with an aneroid manometer (Control Inflator Cuff Pressure manometer, VBM Medizintechnik GmbH, Germany) according to group allocation. The cuff pressure in L group was checked at the pressure to maintain the effective ventilation limiting 25 cmH_2O. The inflated cuff volumes and pressures were recorded along with the number of attempts until successful LMA insertion. An attempt was defined by LMA placement in the mouth. The successful LMA insertion was defined as synchronised expansion of chest wall with unobstructed inspiratory/expiratory flow, normal capnographic tracing at positive pressure ventilation, and no-audible leak at LMA cuff just after LMA insertion. If these criteria were not met after 3 attempts at LMA insertion, the airway was secured according to the decision of the attending anaesthesiologists and the case was defined as an LMA insertion failure. The causes of LMA insertion failure were checked (insertion failure into airway, persistent air leak or ineffective ventilation). After LMA insertion, the patient's head was placed in a neutral position and the oropharyngeal leak pressure (OLP: the pressure at which a gas leak occurs around the airway device) was checked by closing the adjustable pressure-limiting valve of the anaesthesia circuit with manual ventilation at a fixed gas flow of 4 L/min. The OLP was determined when a sound was detected around the mouth by auscultation in equilibrium with the airway pressure of the anaesthesia circuit. If the no sound was heard above 40 cmH_2O, the OLP was reported as 40 cmH_2O. The airway pressure was not allowed to exceed 30 cmH_2O. Anaesthesia was maintained with sevoflurane, titrated to maintain bispectral index values between 40 and 60. During anaesthesia, minimal and maximal end expiratory concentrations of sevoflurane were recorded with a gas analyser. After anaesthesia induction, volume-controlled ventilation with tidal volume 6 mL/kg of ideal body weight and no positive end-expiratory pressure was applied. The respiratory rate was adjusted to keep the partial pressure of end-tidal carbon dioxide between 35 and 40 mmHg. Additional rocuronium was administered under the guidance of the peripheral NMT monitoring. Pneumoperitoneum was generated by carbon dioxide insufflation to a maximum insufflation pressure of 12 mmHg. The LMA cuff pressure was checked with the aneroid manometer immediately after carbon dioxide insufflation and recorded. Peak and mean airway pressures were checked and recorded before carbon dioxide insufflation and rechecked and recorded after ventilator setting to maintain partial pressure of end-tidal carbon dioxide between 35 and 40 mmHg with adjustment of respiration rate but not tidal volume. Sevoflurane and remifentanil were discontinued at the end of the surgery and intravenous ketorolac 0.5 mg/kg was administered for postoperative pain control at operation site. Residual neuromuscular paralysis was antagonised with neostigmine 0.05 mg/kg and glycopyrrolate 0.01 mg/kg under the guidance of the peripheral NMT monitor. Pharyngeal suctioning was not routinely performed. The LMA cuff was completely deflated and the deflated cuff volume was checked using a 50-mL syringe. After LMA removal, the device was inspected for gross blood on the inside or outside surface and patient was transferred to the postanaesthesia care unit (PACU).

If the situation of ventilation failure occurred during the anaesthesia, the airway was secured according to the decision of the attending anaesthesiologists and the case was checked.

2.3. Postoperative Evaluation. Postoperative pain at operation site was assessed at the same points by using a visual analogue scale (VAS) that ranged from 0 to 100 mm with 0 = no pain and 100 = worst pain imaginable. Ketorolac 0.5 mg/kg given intravenously in the PACU or general ward with maximum of

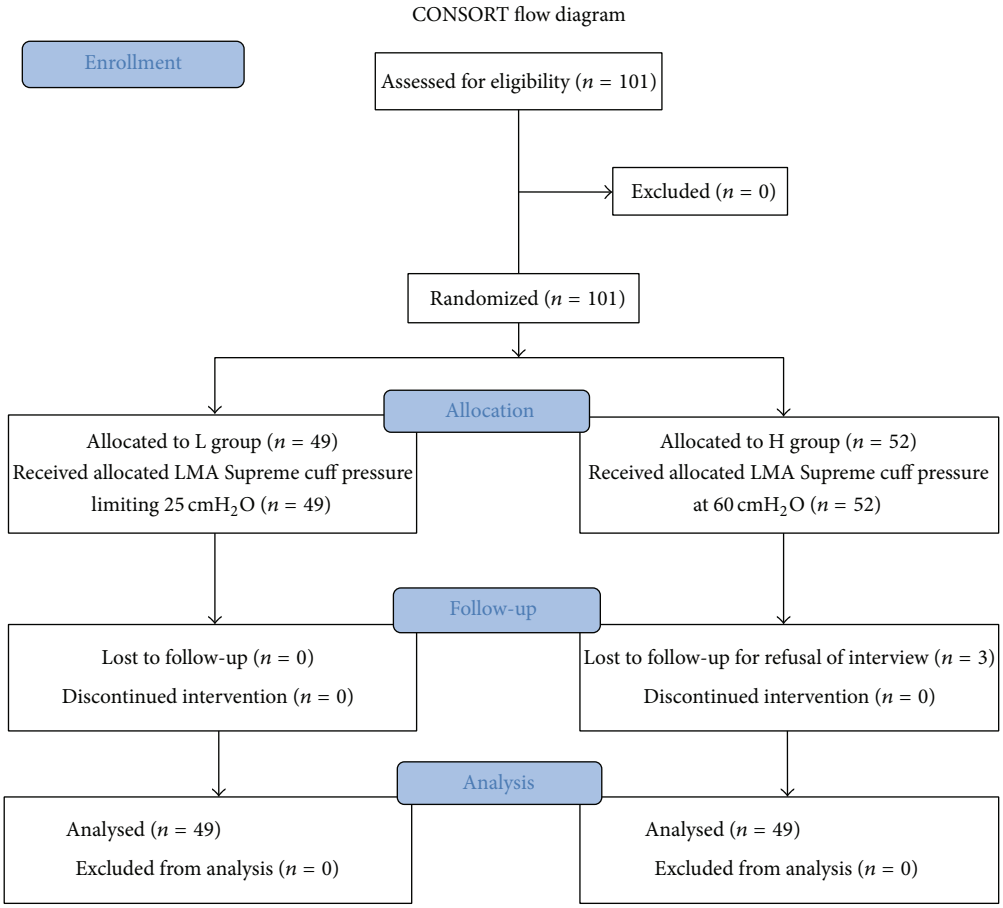

Figure 1: CONSORT flow diagram. LMA: laryngeal mask airway; L group: laryngeal mask airway (LMA) cuff pressure limiting 25 cmH_2O group; H group: LMA cuff pressure at 60 cmH_2O group.

3 doses was given as needed for postoperative analgesia and recorded.

Postoperative pharyngolaryngeal adverse events were assessed: sore throat was defined as constant pain or discomfort in the throat independent of swallowing; dysphonia was defined as difficult speaking or pain on speaking; dysphagia was defined as difficulty or pain provoked by swallowing [8]. The incidence of postoperative pharyngolaryngeal adverse events was recorded at discharge from the PACU (POD 1) and 24 hours after discharge from the PACU (POD 2). Any complications related to LMA insertion, such as recurrent laryngeal nerve palsy, hypoglossal nerve palsy, lingual nerve palsy, and arytenoid cartilage dislocation, were also recorded at POD 1 and POD 2.

Postoperative nausea and vomiting (PONV) was assessed at POD 1 and POD 2 using a 3-point ordinal scale (0 = none, 1 = nausea, 2 = retching, 3 = vomiting) [10]. The severity of PONV was evaluated using a modified Rhodes index at POD 2 [11].

All data were collected by trained observers who did not participate in patient care and were blind to the allocation.

2.4. Statistics. The primary outcome variable was the incidence of sore throat at POD 2. In a pilot study with 20 patients undergoing laparoscopic surgical procedures with the LMA cuff pressure at 60 cmH_2O (H group), sore throat occurred in 8 patients. A minimum detected difference of 75% in the incidence of sore throat between the groups was considered to be of clinical significance. The sample size of 49 was calculated with a power of 0.9 and an α value of 0.05. The data were analysed using Statistical Package for the Social Sciences ver. 11.0 software. The values between two groups were analysed using an unpaired chi-square test as parametric test or Fisher exact test as nonparametric test for categorical variables and Mann-Whitney Rank Sum test as nonparametric test for continuous variables. The intragroup changes between POD 1 and POD 2 were compared with paired t-test as parametric test or Wilcoxon Signed Rank test as nonparametric test. All data were expressed as the number of patients or mean ± standard deviation. A value of $P < 0.05$ was considered statistically significant.

3. Results

From January to August 2012, a total of 101 patients consented to enrolment in the study. However, 3 patients in H group who refused interviews at POD 1 or POD 2 were excluded from the analysis. Therefore, a total of 98 patients were included in the analysis (Figure 1).

Table 1: Demographic data.

	L group	H group	P
Gender (M/F)	18/31	18/31	1.00
Age (yrs)	42 ± 15	41 ± 14	0.828
Height (cm)	164 ± 8	163 ± 7	0.468
Weight (kg)	64 ± 13	65 ± 11	0.592
Operation			0.686
Appendectomy	6	9	
Cholecystectomy	34	34	
Gynecological	9	6	
CO_2 pr (mmHg)	12	12	
Time (min)			
Anesthesia	86 ± 31	86 ± 32	0.962
Operation	56 ± 30	58 ± 31	0.767
LMA size			0.299
Size 3	7	3	
Size 4	36	39	
Size 5	6	7	
Attempt number			0.399
1	47	45	
2	2	4	
3	0	0	
Insertion failure			—
Into airway	0	0	—
Air leak	0	0	—
Ineffective V	0	0	—
Blood on LMA	3	4	0.698
Sevoflurane			
Min (%)	0.9 ± 0.2	1.0 ± 0.4	0.76
Max (%)	1.7 ± 0.3	1.6 ± 0.3	0.63
Op site pain			
POD 1	40 ± 6	32 ± 5	0.86
POD 2	40 ± 8	34 ± 7	0.30
Ketorolac (mg)			
~POD 1	16 ± 17	12 ± 17	0.88
POD 1~POD 2	11 ± 16	7 ± 14	0.80

Values are expressed as number of patients or mean ± standard deviation.
L group: laryngeal mask airway (LMA) cuff pressure limiting 25 cmH_2O group; H group: LMA cuff pressure at 60 cmH_2O group; M: male; F: female; CO_2 pr: insufflated carbon dioxide pressure for pneumoperitoneum, time, attempt number, and attempt number for successful LMA insertion; Into airway: failure into airway; Air leak: persistent air leak; Ineffective V: ineffective ventilation; Blood stained LMA: the presence of visible blood inside or outside of LMA; Min (%): minimal end expiratory concentrations of sevoflurane concentration (%); Max (%): maximal end expiratory concentration of sevoflurane (%); Op; operation; POD 1: postoperative day 1 (discharge from postanaesthetic care unit (PACU)); POD 2: postoperative day 2 (24 hours after discharge from PACU); ~POD 1: from end of surgery to discharge from PACU; POD 1~POD 2: from POD 1 to POD 2.

Demographic data between the groups were similar (Table 1).

Intraoperative measurements and recordings are presented in Table 2. The cuff volume and pressure before pneumoperitoneum showed significant difference between the two groups (volume: 19.5 ± 3.5 mL, L group versus 31.0 ± 3.6 mL, H group; $P < 0.001$; pressure: 18.6 ± 2.5 cmH_2O, L group versus 55.9 ± 3.2 cmH_2O, H group; $P < 0.001$). The OLP in the L group was significantly lower than that in the H group (27.2 ± 7.0 cmH_2O versus 31.1 ± 9.7 cmH_2O, $P = 0.025$) before pneumoperitoneum. There were no significant differences between the two groups in peak and mean airway pressures before pneumoperitoneum. After pneumoperitoneum with carbon dioxide insufflation, the LMA cuff pressure showed significant difference between the two groups (18.8 ± 4.0 cmH_2O, L group versus 56.0 ± 4.8 cmH_2O, H group; $P < 0.001$), but OLP and peak and mean airway pressures after pneumoperitoneum had no significant difference between two groups. Intragroup changes before and after pneumoperitoneum followed as below: changes of cuff pressure with carbon dioxide insufflation showed no differences in either group ($P = 0.651$ in L group and $P = 0.937$ in H group); OLP was significantly increased with carbon dioxide insufflation in the L group (27.2 ± 7.0 to 29.0 ± 8.1, $P = 0.028$) but had no significant change in the H group (31.1 ± 9.7 to 31.3 ± 9.9, $P = 0.653$) (Figure 2); peak and mean airway pressures were significantly increased after carbon dioxide insufflation in both groups ($P < 0.0001$). The cuff volume after LMA removal was significantly lower in the L group than in the H group (19.5 ± 3.5 mL, L group versus 31.4 ± 3.5 mL, H group; $P < 0.0001$) with no changes in cuff volumes at LMA insertion in either group.

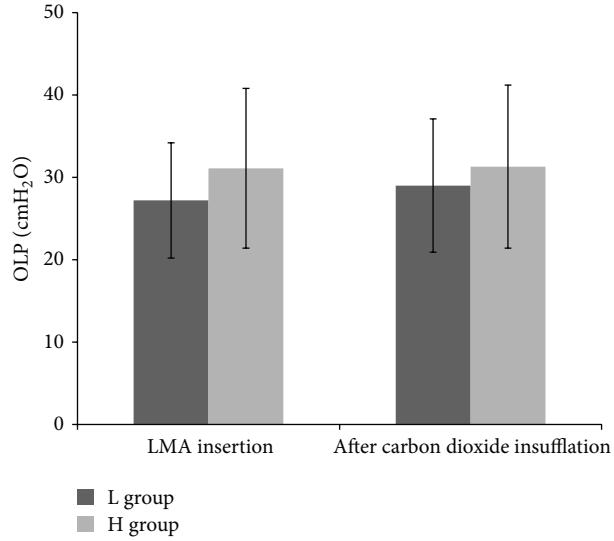

Figure 2: Changes of oropharyngeal leak pressure (OLP) before and after pneumoperitoneum with carbon dioxide (CO_2) insufflation. LMA: laryngeal mask airway; L group: laryngeal mask airway (LMA) cuff pressure limiting 25 cmH_2O group; H group: LMA cuff pressure at 60 cmH_2O group.

All patients tolerated LMA well and there were no cases of ventilation failure. Three patients in each group had visible blood inside or outside the LMA device after LMA removal.

Details of postoperative pharyngolaryngeal adverse events are presented in Table 3. Postoperative sore throat at

Table 2: Laryngeal mask airway (LMA) parameters compared between low and high LMA cuff pressures.

	LMA insertion		P	After CO_2		P	LMA removal		P
	L group	H group		L group	H group		L group	H group	
LMA cuff									
Vol (ml)	19.5 ± 3.5	31.0 ± 3.6	<0.001	—	—	—	19.5 ± 3.5	31.4 ± 3.5	<0.001
Pr (cmH_2O)	18.6 ± 2.5	55.9 ± 3.2	<0.001	18.8 ± 4.0	56.0 ± 4.8	<0.001	—	—	—
OLP (cmH_2O)	27.2 ± 7.0	31.1 ± 9.7	0.025	29.0 ± 8.1	31.3 ± 9.9	0.208	—	—	—
Airway pr (cmH_2O)									
Peak	12.1 ± 2.6	13.0 ± 2.6	0.106	17.0 ± 4.1	18.4 ± 3.8	0.106	—	—	—
Mean	5.3 ± 0.9	5.6 ± 1.2	0.109	6.5 ± 1.3	7.0 ± 1.5	0.154	—	—	—

Values are expressed as mean ± standard deviation.
After CO_2: after carbon dioxide insufflation; L group: laryngeal mask airway (LMA) cuff pressure limiting 25 cmH_2O group; H group: LMA cuff pressure at 60 cmH_2O group; Vol: volume of air for LMA cuff inflation; Pr: pressure of air for LMA cuff inflation; OLP: oropharyngeal leak pressure; Airway pr: airway pressure.

Table 3: Postoperative pharyngolaryngeal adverse events.

	POD 1		P	POD 2		P
	L group	H group		L group	H group	
Sore throat	2	6	0.140	3	12	0.012
Dysphonia	0	0	—	0	1	0.315
Dysphagia	0	4	0.041	0	4	0.041
Cx	0	0	—	0	0	—

Values are expressed as number of patients.
L group: laryngeal mask airway (LMA) cuff pressure limiting 25 cmH_2O group; H group: LMA cuff pressure at 60 cmH_2O group; POD 1: postoperative day 1 (discharge from postanaesthetic care unit); POD 2: postoperative day 2 (24 hours after discharge from postanaesthetic care unit); Cx: any complications related with laryngeal mask airway insertion.

Table 4: Postoperative nausea and vomiting (PONV).

	POD 1		P	POD 2		P
	L group	H group		L group	H group	
PONV			0.461			0.509
None	40	37		42	37	
Nausea	7	9		3	6	
Retching	2	3		3	3	
Vomiting	0	0		1	3	
Rhodes index	0.6 ± 1.7	0.8 ± 1.6	0.592	1.3 ± 4.0	2.0 ± 4.8	0.443

Values are expressed as number of patients or mean ± standard deviation.
L group: laryngeal mask airway (LMA) cuff pressure limiting 25 cmH_2O group; H group: LMA cuff pressure at 60 cmH_2O group; POD 1: postoperative day 1 (discharge from postanaesthetic care unit); POD 2: postoperative day 2 (24 hours after discharge from postanaesthetic care unit).

POD 2 was significantly lower in the L group (6.1%) than in the H group (24.5%) ($P = 0.012$). Postoperative dysphagia at POD 1 and POD 2 was also lower in the L group (0.0%) than in the H group (8.2%) ($P = 0.041$). One patient in the H group had dysphonia at POD 2, but there was no significant difference between groups. No complications related to LMA insertion were reported in either group.

The incidence of PONV was 18.4% in the L group and 24.5% in the H group at POD 1 and 14.3% (L group) and 24.5% (H group) at POD 2. However, the incidence of PONV assessed using a three-point ordinal scale and Rhodes index at POD 1 and POD 2 showed no significant differences between the two groups (Table 4).

4. Discussion

The present study demonstrated that LMA cuff pressure limiting 25 cmH_2O decreased the incidence of postoperative pharyngolaryngeal adverse events, specifically sore throat and dysphagia, without intraoperative ventilatory failure with a lower OLP, using LMA Supreme.

As cuff pressure of ETT or LMA devices increases, perfusion of the airway mucosa is progressively decreased, which results in postoperative pharyngolaryngeal adverse events [12]. Therefore, limiting cuff pressures of airway devices can reduce postoperative pharyngolaryngeal adverse events [5–7]. Seet et al. performed a study similar to the present study and determined that LMA cuff pressures below 40 mmHg (60 cmH_2O) were associated with reduced incidence of postoperative pharyngolaryngeal complications [4], but 60 cmH_2O was still the higher limit in terms of airway perfusion pressure. Seet et al. had a lower incidence of sore throat (3.1% in 97 patients) and dysphagia (2.1% in 97 patients) at postoperative 24 hours in the pressure limiting group, compared with H group applying the same cuff pressure in the present study (sore throat of 24.5% and dysphagia of 8.2% in 49 patients). The cause would be associated with characteristics of postoperative analgesic. Seet et al. used opioid (fentanyl 25 μg) for postoperative analgesic, while we used a nonsteroidal anti-inflammatory drug (NSAID, ketorolac 0.5 mg/kg). The low potency of the NSAID compared with the opioid [13] could have resulted in the higher incidences of sore throat and dysphagia in the present study. Zhang et al. showed that LMA Supreme cuff pressure of 80 cmH_2O was not associated with higher incidence of postoperative pharyngolaryngeal adverse events [3]. Zhang et al. also used an opioid (fentanyl 25 μg) as the postoperative analgesic. The higher incidence of sore throat at POD 2 than POD 1 would be associated with recovery from anaesthesia. The concern of postoperative pain at operation

site would be converted into pain at other sites as the patient recovered from anaesthesia.

Regarding dysphonia, the LMA is a supraglottic airway device and the occurrence of dysphonia is rare. However, there is risk that a pressure neuropraxia from the LMA cuff can result in dysphonia [14–16]. The portion of the recurrent laryngeal nerve that is vulnerable to damage by the LMA is in the cricoid cartilage at the lower part of the piriform fossa [15]. When the LMA is precisely positioned, its tip will be resting against the upper oesophageal sphincter with the sides facing the piriform fossa [17]. Seet et al. reported dysphonia of 4.1% in pressure limiting group and 6.8% in routine care group. However, the LMA cuff pressure limiting 25 cmH_2O in the present showed no occurrence of dysphonia. It would demonstrate that the cuff pressure of LMA could influence the occurrence of dysphonia.

The airway security between airway device and pharynx must be firstly considered before the postoperative pharyngolaryngeal adverse events. We demonstrated that the limited cuff pressure with 25 cmH_2O safely secured airway, especially in laparoscopic surgical procedures. LMA use in laparoscopic surgical procedures has previously been restricted or contraindicated [18]. However, several researchers have proven the safety of LMA in laparoscopic surgical procedures [19, 20]. When an LMA Supreme is correctly positioned, the tip of the device serves as second seal at the top of the oesophagus over upper oesophageal sphincter [2, 21]. In the present study, a peak airway pressure not exceeding 20 cmH_2O with an OLP of about 30 cmH_2O and maintenance of effective ventilation after pneumoperitoneum in both groups was taken to indicate that the LMA was correctly positioned, although the visible evaluation for correct position of LMA was not performed. Gastric distension is a main cause in PONV [22]. The insignificant difference in the incidence of PONV between the two groups in the present study indicated that the limited cuff pressures with 25 cmH_2O had an effective sealing effect of the airway, comparable with the higher cuff pressure at 60 cmH_2O.

However, one consideration remains. OLP in both groups was increased after carbon dioxide insufflation. This was thought to be associated with the increased intra-abdominal pressure causing a morphologic change of the pharynx at the well-fitted LMA or a change of the LMA cuff at the well-fitted pharynx. Either way, the change of pharynx or LMA cuff might have resulted in the increased OLP. In the present study, we measured the cuff volume at LMA insertion and LMA removal. Almost the same volume at LMA insertion and LMA removal could rule out the effect of carbon dioxide diffusion into cuff of LMA with pneumoperitoneum.

Two limitations had to be considered. Firstly, the incidence of sore throat at POD 2 with 24.5% in H group was different with the pilot study (40% with 8 patients from 20 patients). The difference would need more or less sample size, although the sample size with 47 patients for each group in the present study was larger than the sample size with 40 patients for each group in Zhang at al. [3]. Lastly, the majority of the patients enrolled in the present study were undergoing laparoscopic cholecystectomy. For better visualisation, the standard position for this procedure is head-up and left-side tilted. This position would lessen the effects of the pneumoperitoneum on the LMA cuff. In addition, there were no extremely obese patients included in the present study. Cuff pressures in extremely obese patients in Trendelenburg position would be strongly influenced and would be expected to yield different results than those demonstrated here. Shorter anaesthesia time may also have influenced the results of the present study, although an LMA is usually not chosen for airway management when longer anaesthesia times are anticipated [18].

5. Conclusions

LMA cuff pressure limiting 25 cmH_2O allowed safe airway management with secure airway and lower incidence of postoperative pharyngolaryngeal adverse events compared with cuff pressure at 60 cmH_2O, using LMA Supreme.

Disclosure

The study was presented as poster at American Society of Anesthesiologists 2013 Annual Meeting (San Francisco, October 12–October 16).

Conflict of Interests

The authors declare that there is no conflict of interests regarding the publication of this paper.

Authors' Contribution

All authors read and accepted the terms and conditions of The Scientific World Journal and were responsible for collection of data. Joo-Eun Kang, M.D., Chung-Sik Oh, M.D., and Seong-Hyop Kim, M.D., Ph.D., were responsible for analysis and interpretation of data. Joo-Eun Kang, M.D., and Seong-Hyop Kim, M.D., Ph.D., were responsible for description of the paper. Seong-Hyop Kim, M.D., Ph.D., was responsible for design of the study.

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