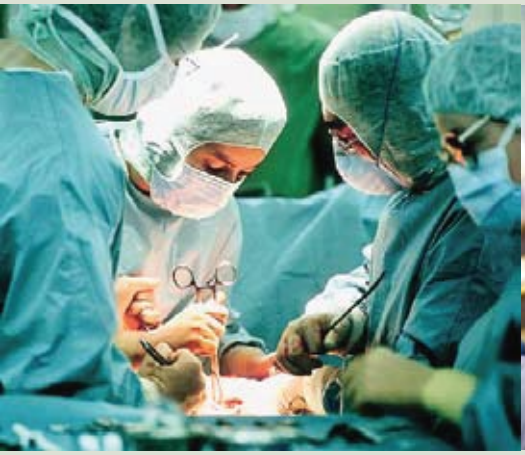
AMBULATORY SURGERY

International Journal covering Surgery, Anaesthesiology, Nursing and Management Issues in Day Surgery




The Official Clinical Journal of the
INTERNATIONAL ASSOCIATION
FOR AMBULATORY SURGERY

VOLUME 14.1 APRIL 2008

AMBULATORY SURGERY

VOLUME 14.1

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Editorial: **Progressing Ambulatory Surgery**

Paul Jarrett

At the start of the second year of electronic publication, we would like to thank all the authors who have contributed papers and to encourage these and others to continue to submit their work in the future. Hopefully, we have gradually improved the format of the Journal thanks to the hard work of Dr. Claus Toftgaard and Thomas Toftgaard who undertake the electronic publishing.

We wish also to improve and expand the content of the Journal. To this end we would like to receive the following:

- Correspondence from our readers, either additive or critical, concerning articles that have been published.
- Readers' views on subjects that should be covered in future review articles.
- Review articles on national or other ambulatory surgery meetings.
- Brief updates on day surgery activity and contentious issues in individual countries.
- Readers' suggestions for any changes or additions that they feel would improve the Journal.

The relevance and vibrancy of a journal depends on the active involvement of its readers and contributors. We hope that all those with an interest in ambulatory surgery will become involved with Ambulatory Surgery and adopt it as their journal of choice both for publishing their work and for exchanging ideas and information.

Paul E. M. Jarrett

Joint Editor-in-Chief

LigaSure-assisted versus diathermy day case haemorroidectomy: a randomized controlled trial

K.L. Fok, M.H.Y. Cheung, C.M. Poon, K.W. Lee

Abstract

Aim: Milligan-Morgan haemorrhoidectomy is considered the best treatment for haemorrhoidal disease. The major drawback is severe post-operative pain. We postulate that using the LigaSure™ vessel sealing system to divide the haemorrhoidal pedicle may cause less postoperative pain.

Methods: This was a double-blinded randomised controlled trial in a single institution. Consecutive patients undergoing elective day-case haemorrhoidectomy were recruited. Patients were randomised into the diathermy (D) group or the LigaSure™ (L) group. The haemorrhoidal pedicle was coagulated with monopolar diathermy in D group or the LigaSure vessel sealing system in L group. Patients were seen in post-operative weeks 1, 3, 6 and 12 for assessment. Primary outcome was post-operative pain by 10cm visual analog pain score. Secondary outcomes include operative time, complications and day discharge rate.

Results: 68 patients were recruited in this study (n=33 in D group versus n=35 in L group) with comparable demographic data. There was no significant difference in VAS pain score (median postoperative one-week cumulative pain score: D group = 40.2 versus L group = 39, p=0.93). More complications were observed in D group (5 versus 2, p=0.25) but this was not statistically significant. Day discharge rate was similar in the two groups at about 88%. **Conclusion:** Ligasure-assisted haemorrhoidectomy is not superior to diathermy haemorrhoidectomy. Day case haemorrhoidectomy is feasible and safe with both techniques.

Keywords: Haemorrhoidectomy; Post-operative pain; LigaSure; Faecal incontinence.

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Introduction

Milligan-Morgan haemorrhoidectomy is considered the best treatment for haemorrhoidal disease [1]. It is also renowned for its severe post-operative pain especially during the first post-operative week. It is postulated to be due to septic complications and sphincter spasm [2,3]. Antibiotic regimens and topical nitrates have been used for minimizing post-operative pain, but the results are not conclusive [3-5]. LigaSure™ is a bipolar vessel sealing system using high current and low voltage electrical power to reform vessel collagen and elastin to seal the vessel. The instant feedback system adjusts energy delivery according to tissue reaction with a frequency of 200 times/sec and has minimal charring effect and thermal spread of 2–5mm [6,7].

Based on the assumptions that precise and appropriate current delivery may provoke less thermal injury to the sphincter and its surrounding tissue and therefore produce less sphincter spasm, we postulated that using the LigaSure™ vessel sealing system in controlling the haemorrhoidal pedicle may cause less post-operative pain than the conventional diathermy technique.

Patients and method

This was a double-blinded randomised controlled trial in a single institution from 1 July 2002 to 30 June 2003 with the approval of the ethics committee. All patients undergoing elective day case haemorrhoidectomy were recruited to this study. Patients with a past history of haemorrhoidectomy, age older than 75 years, or with other concomitant anorectal pathology were excluded from the study. Eligible patients with informed consent were randomised using computer generated numbers in sealed opaque envelopes into two groups at the time of anaesthesia. Patients were blinded to the result of randomisation. All operations were performed under spinal anaesthesia in the lithotomy position by colorectal surgeons. Anaesthetic technique and surgical technique on dissection of the haemorrhoidal pedicle were standardised in both groups. 2% lignocaine with 1:10000 adrenaline was infiltrated into the perianal skin to facilitate identification of the submucosal plane. Haemorrhoidectomy was performed using monopolar diathermy in cutting mode with the power of 25W. The haemorrhoidal pedicle was dissected from the internal sphincter to its apex. In the control group, the pedicle was coagulated with monopolar diathermy and divided with scissors. In the treatment arm, we used the medium-size LigaSure™ vessel sealing system to coagulate the pedicle which was then divided with scissors. A one centimetre mucocutaneous bridge between pedicles was ensured. Xylocaine jelly was applied to the wound at the end of the procedure. No wound packing was required in either group.

The operative time and the number of piles excised were documented by an independent assessor who was blinded to the randomisation results. Patients were discharged in the afternoon when they were ambulatory and able to pass urine. Dologesic (500mg 4 times daily as required for 28 tablets), Flagyl 400mg three times 4 daily for 5 days, 4% potassium permanganate sitz bath and Metamucil 2 teaspoons three times daily as required were given upon discharge. Patients were asked to follow-up in our specialty clinic in post-operative weeks 1, 3, 6 and 12 and assessed by independent specialists.

The primary outcome was post-operative pain. Patients charted their pain score using 10cm visual analog scale from day 1 to day 7 after the operation. Patients were asked to bring back any remaining Dologesic tablets to their first follow up, where the analgesia consumption was counted and recorded. Complications including faecal incontinence, per-rectal bleeding, and readmission were compared. Faecal incontinence was assessed using the Pescatori score system [8].

Statistics

30 patients should be recruited in each group to identify an improvement of 50% in one-week cumulative pain score, with a power of 0.8 and p-value of 0.05. Continuous variables were analysed by Mann-Whitney U test and categorical variables were analysed by Chi-square test or Fisher Exact test as appropriate using SPSS 9.0 for window.

Results

A total of 68 patients were recruited in this study. (diathermy (D) group= 33, LigaSure™ (L) group =35). There was no significant difference between the two groups in respect of mean age, sex distribution or the number of piles excised. (Table 1). Median operative time was similar between two groups (D=20mins. [3–45] versus L=20mins. [4–37], p=0.17). There was no significant difference in the median post-operative one-week cumulative pain score between the two groups (D=40.2(1–35) versus L=39(1.3–68.8), p=0.93). The daily post-operative pain score and analgesia consumption were similar in the two groups (Table 2).

Table 1 Demographic of the Diathermy (D) Group and the LigaSure™ (L) group.

	Diathermy (D)	Group LigaSure™ (L) group	P value
Age	45.3	46	0.77
Sex (M:F)	1:2.8	1:2.2	0.55
Number of piles excised	2.76	2.57	0.17

Table 2 Post-operative VAS pain score and analgesia requirement.

	Diathermy (D) Group	LigaSure™ (L) group	P value
Day 1	5.0	5.2	0.96
Day 2	6.7	6.5	0.84
Day 3	6.5	6.4	0.31
Day 4	5.8	5.8	0.46
Day 5	5.3	5.8	0.72
Day 6	5.0	5.5	0.67
Day 7	4.9	5.0	0.61
Analgesia requirement (number of Dologesic tablet taken)	18	15.5	0.83

There were more post-operative complications observed in D group. (n=5, urinary retention=1, flatus incontinence=2, transient liquid incontinence=1 for 6 weeks). There were only 2 complications in the L group (urinary retention=1, faecal impaction=1). However, this did not reach the level of significance (D=5 versus L=2, p=0.25, Fisher's exact test). On subgroup analysis, the incontinence rate was higher in the D group but did not reach the level of significance (D=3 versus L=0, P=0.11, Fisher's exact test). Flatus or liquid incontinence subsided within 8 weeks in all patients with these complications. There was no re-bleeding in either group.

Most patients could be discharged on the same day in both groups. (D=29/33 versus L=31/35, p=0.93, Chi square test). One patient in each group was re-admitted for urinary retention and faecal impaction respectively (p=1.0, Fisher's exact test).

Discussion

Despite the apparent short term success in stapled haemorrhoidectomy [9,10,11], the Milligan-Morgan haemorrhoidectomy remains the gold standard of piles treatment with a low recurrence rate [1]. The major drawback of this ablative perianal procedure is postoperative pain. Being one of the most common general surgical procedures, it is also graded as one of the most painful procedures in surgical practice. As in other perianal operations, two major explanations are proposed for the severe pain, namely perianal sepsis and anal sphincter spasm [2,3,4,5,12]. The theoretical advantages of the LigaSure vessel sealing system over convention diathermy are the reliable haemostatic effect and the short distance of current leak (less than 3 mm) which should cause less post-operative sphincter spasm and subsequent pain [6,7].

However, we did not demonstrate any significant advantage in post-operative pain in the LigaSure group. This is similar to past studies that have shown LigaSure offers no benefit in pain control in haemorroidectomy [13,15–17]. We believe that positive identification of the internal anal sphincter by conventional dissection of the submucosal plane can reduce anal sphincter injury, and thus the pain. A careful dissection and preservation of the anal sphincter is more important than the choice of instruments in haemorrhoidectomy. Stapled haemorrhoidectomy is a less painful operation compared with conventional hemorrhoidectomy [9–11]. This is probably due to the absence of an open wound and no dissection of the anal sphincter. Nevertheless, no benefit is shown in the day case setting in stapled haemorrhoidectomy [18,19]. In a study of 168 day case stapled haemorrhoidectomies, only 87.3% were discharged successfully on a day case basis [20]. In our study, a day discharge rate of 88% was achieved in both groups. Day case open haemorrhoidectomy with either LigaSure or diathermy is feasible with acceptable postoperative pain.

One study on long term follow up of LigaSure versus diathermy haemorrhoidectomy showed a significant lower internal anal sphincter thickness and a significant lower volume of rectal urge sensation in the diathermy group [15]. However, it was not clinically significant. The theoretical advantage of Ligasure in causing less sphincter damage and faecal incontinence is not shown in our study. There was no faecal incontinence in either group at 8 weeks after operation. Again, surgical technique in anal sphincter protection is the first priority in the prevention of incontinence complications.

Conclusion

LigaSure-assisted haemorrhoidectomy is not advantageous to diathermy haemorrhoidectomy with similar postoperative pain score and complications. Open haemorrhoidectomy performed with either techniques is feasible and safe as day-case setting. Considering the cost and benefit of LigaSure device, diathermy haemorrhoidectomy is the preferred choice of technique.

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Can we find predictive factors for unplanned overnight admission?

F. Barros, M. Monteiro*, M.E. Matos†, P. Lemos**

Abstract

Aim: To identify risk factors for unplanned admission following ambulatory surgery.

Methods: Case-control analysis, involving 6740 patients from our Day Surgery Unit, between 2001 and 2005. Variables investigated were: gender, age, ASA classification, type of anaesthetic, surgical speciality, duration of anaesthesia, pain, nausea/vomiting, haemorrhage, and anaesthetic consultation. Chi-square tests were first performed for each variable. Afterwards, logistic regression was carried out on those variables found significant.

Results: The unplanned admission rate was 0.8% . Factors associated with admission were: gynaecological surgery, nausea/vomiting, bleeding, severe pain and duration of anaesthesia >120 minutes.

Conclusion: The acknowledgement of risk factors such as these may improve the safety and efficacy of day surgery.

Keywords: Ambulatory surgery; Ambulatory surgical procedures; Patient admission; Post-operative complications; Quality indicators.

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Introduction

Ambulatory surgery has been growing exponentially. In 1985, in the United States, 30% of elective surgery was performed on an ambulatory basis. Currently, this value is 60% and is expected to increase over 70% in the near future [1]. In Portugal, from 1999 to 2005, the percentage of elective surgery performed in the outpatient surgical setting increased 4-fold, reaching 22% in 2005 [2]. The range of acceptable ambulatory surgery procedures has also been expanding, as has the medical complexity of the patients being treated. In order to keep pace with this trend, anaesthetic and surgical techniques have been evolving to maintain or improve the desired outcomes [1, 3-5].

The unexpected hospital admission rate after outpatient surgery is a method of evaluating these outcomes, and also an important morbidity and quality indicator [1, 6]. Not only does hospital admission following ambulatory surgery likely to represent an adverse clinical situation, but it also adds to costs and disrupts both surgical and inpatient facility routines. The main objective of this study was to identify the factors that independently affected hospital admission at our day surgery unit. The incidence of hospital admission and its underlying causes were also evaluated.

Material and Methods

Hospital Geral de Santo António is a tertiary care and university hospital. Its hospital based day surgery unit (DSU) has 2 operating rooms, a 4 bed post-anaesthesia care unit, and a phase II recovery area with 12 beds and 8 reclining chairs. The annual caseload is, on average, 1600 patients. Operative procedures performed cover general surgery, vascular surgery, dermatology, gynaecology, neurosurgery, neuropathology, orthopaedic surgery and urology. The main surgical activity occurs from 8:30 A.M. to 02:00 P.M., Monday through Friday. After 02:00 P.M. minor surgery under local anaesthesia is performed without the presence of an anaesthetist. The Phase II recovery area is open until 08:00 PM. Discharge criteria comply with the post-anaesthesia discharge scoring system (PADSS) and, therefore, require a score of 9 or greater, in addition to an adult escort, to consider the patient fit for discharge home. Otherwise, patients are admitted to the hospital. This latter situation represents an unplanned overnight admission.

The DSU keeps an updated clinical database for quality control purposes, comprising all the patients submitted to surgery under anaesthesia. This database does not include patients submitted to minor surgery, in the afternoon.

From this database, we carried out a case-control study involving all the patients that underwent surgery at the DSU from the 3rd January 2001 to the 13th December 2005, 6740 patients in total.

The control group consisted of all the patients discharged home from the DSU during the period studied.

Events following hospital admission or the re-admission rate were not investigated. As there were no human subjects involved, and patients' identification in the database was kept concealed, informed consent was not sought, nor ethical review committee approval.

For each patient we considered only one cause for admission. In case there was more than one, the most serious cause, from a clinical point of view, was considered. Reasons for admission were classified as surgical, anaesthetic, medical or social.

Variables investigated were gender, age, American Society of Anesthesiologists (ASA) physical status classification, type of anaesthesia, surgical speciality, duration of anaesthesia, post-operative pain, post-operative nausea and vomiting, haemorrhage and pre-operative anaesthesia consultation.

The type of anaesthesia was classified as general, regional, combined general-regional technique or sedation along with local anaesthesia.

The duration of anaesthesia was defined as the length of time between induction and emergence in the operating room.

Because of the small number of admissions separately related to dermatology, neurosurgery, neuropathology and orthopaedics, these were gathered in a single group for statistical analysis.

Although post-operative pain was evaluated according to the visual analog scale (VAS), it was recorded in a categorical scale as mild (VAS ≤3), moderate (VAS 4-6) or severe (VAS >6). We assumed for each

patient the most severe pain experienced during the DSU stay. Nausea and vomiting situations recorded consisted of those patients with relevant nausea, isolated vomiting, or vomiting episodes.

Haemorrhage consisted of any degree of peri-operative bleeding considered significant by the surgeon, or that impelled an action like dressing change or wound re-closure.

The decision to refer patients for an anaesthesia consultation was left to the surgeon's discretion, but healthy patients (ASA I) were excused that appointment. Statistical analysis consisted of a two stage process.

First, we performed an univariate analysis, through separate chi-square tests, to investigate the relationship between each variable and hospital admission. Next, we performed a multivariate analysis using the variables that were associated with hospital admission in the previous chisquare tests ($P < 0.05$). In this latter analysis, we used logistic regression to determine which variables were independently related to hospital admission. Using this method we were able to describe the magnitude of each relationship, and control for the influence of confounding variables in the statistical model. Odds ratios, 95% confidence intervals and P values were thus calculated for each variable in the regression model. If the 95% confidence interval did not include 1, or $P < 0.05$, the corresponding variable was considered a risk factor for hospital admission.

Statistical analysis was performed using SPSS 12.0 for Windows (SPSS Inc., Chicago, IL, EUA)

Results

The incidence of hospital admission was 0.8% (n = 55). Fifty eight per cent of patients were evaluated at an anaesthesia consultation. Patients' age ranged from 6 months to 89 years, mean and standard deviation (SD) were 41 ± 17 years old. Most patients were ASA I or II (46 and 45%, respectively), but also ASA III (7%), and even ASA IV (2%). ASA IV patients consisted of end-stage chronic renal failure patients on dialysis, submitted to brachial artery to axillary vein jump graft, or placement of a Tenckhoff catheter. Female gender (56%) was predominant.

7013 surgical procedures were performed. General surgery was responsible for most patients (Table 1), but surgical treatment of varicose veins was the most frequently performed surgical procedure (Table 2). The most complex operations included thyroid lobectomy, laparoscopic cholecystectomy, and lumbar microdiscectomy (Table 3).

Table 1 Distribution of patients by surgical speciality.

Surgical speciality	Patients (n = 6740) Number (%)
General surgery	3077 (45.7)
Vascular surgery	924 (14.0)
Dermatology	6 (0.1)
Gynaecology	808 (11.8)
Neurosurgery	149 (2.4)
Neuropathology	256 (3.8)
Orthopaedics	962 (13.8)
Urology	558 (8.4)

Table 2 Most frequent surgical procedures.

Type of procedure	Number (%)
Surgical treatment of varicose veins	1024 (14.6)
Surgical treatment of pilonidal disease	698 (10.0)
Inguinal hernia repair	586 (8.4)
Median nerve decompression	497 (7.1)
Laparoscopic tubal ligation	474 (6.8)
Haemorrhoidectomy	261 (3.9)
Total number of procedures = 7013	

Table 3 Most complex surgical procedures.

Type of procedure	Number (%)
Thyroid lobectomy	153 (2.8)
Laparoscopic cholecystectomy	77 (1.1)
Lumbar microdiscectomy	66 (0.9)
Brachial artery to axillary vein jump graft	47 (0.7)
Cranioplasty	11 (0.2)
Total number of procedures = 7013	

Table 4 Causes for admission (N = 55).

Causes	Number (%)
Surgical (n = 40)	(72.7)
Bleeding control	20
Postoperative ileus control	7
Bowel perforation	3
Extensive surgery	5
Uterine perforation	1
Wound oedema	1
Sensory/motor deficit	1
Peripheral nerve block	1
Dural perforation	1
Anaesthetic (n = 5)	(9.1)
Nausea & vomiting	4
Pain	1
Medical (n = 6)	(10.9)
Hypoxaemia	3
Anxiety	2
Faintness	1
Social (n = 4)	(7.3)
Discharge refusal by the patient	2
Other	2

General anaesthesia was the most frequent anaesthetic technique (56%). Combined anaesthesia was used in 19% of patients. Sedation with local anaesthesia was the anaesthetic option in 16% of cases. Duration of anaesthesia ranged between 10 minutes and 4 hours, mean and SD were 49 ± 27 minutes.

Most common reasons for admission were related to surgery (Table 4).

Univariate analysis revealed that gender, age, ASA status and anaesthesia consultation were not associated with hospital admission. On the contrary, surgical speciality, type of anaesthesia, duration of anaesthesia, post-operative pain, post-operative nausea and vomiting, and haemorrhage were statistically significant (Table 5).

After logistic regression, the variables still associated with hospital admission were surgical speciality, duration of anaesthesia, pain, nausea and vomiting, and haemorrhage (Table 6).

The type of anaesthesia was not independently related to hospital admission. In the case of pain, only the most severe pain influenced admission. Table 6 shows, through odds ratios, the relative weight of each predictive factor on admission. Risk of admission is directly related to the duration of anaesthesia, and rises exponentially.

Discussion

The incidence of hospital admission at our DSU (0.8%) is similar to the average value mentioned in the literature (1%) [6]. However, the heterogeneity of ambulatory surgery programmes may preclude comparisons. Low rates of admission make studies about predictive factors more demanding because they require larger numbers of patients. Despite being a case-control study, data came from a pre-existing prospective and updated database. That circumstance enabled us to get complete information concerning every patient. Moreover, all discharged patients served as controls, making matching unnecessary. Nevertheless, the retrospective nature of the study and the unrelated original purpose of the existing database, created shortcomings, namely, exclusion of other risk factors, e.g., ending hour of surgery [7, 14], previous abdominal surgery [8] or pre-operative haemoglobin concentation [8].

In our study, every surgical procedure was planned to end at 02:00 P.M.

We chose to investigate the effect of the type of surgery through surgical speciality, like others have done [7, 9, 10, 11], but this option was not consensual [12, 13].

Age, gender, ASA status and anaesthesia consultation were not predictive factors of hospital admission.

In the study of Gold et al [12] age was a predictive factor (30 year intervals). Mingus et al [9] reached the same conclusion (age greater than 65 years) but only for surgery lasting less than 60 minutes. The findings of Fortier et al [7], Twersky et al [11], Linares et al [13] were in accord with our results.

In one study [11], female gender was a predictive factor of avoidable admission, i.e., for social or administrative reasons. But another [7] concluded that male gender affected admission.

The lack of influence of ASA status on hospital admission was also a conclusion of one other study[11]. One explanation ascribes this finding to a selection bias. Only stable patients are accepted for outpatient surgery. Nonetheless, Fortier et al [7] and Linares et al [13] found that ASA II and III patients were more likely to be admitted than ASA I patients. Mingus et al [9] reached the same conclusion (ASA III and IV vs. I and II) for surgery lasting less than 60 minutes. Regarding ASA IV patients, only Mingus et al [9] refered to their inclusion. Could this circumstance be attributed to controversies in ASA classification? Specifically, how to classify end-stage renal disease patients on dialysis, ASA III or IV? In any event, a critical and proper selection of patients should not result in higher admission rates for ASA III or IV patients.

Evidence that the type of anaesthesia was not a predictive factor of hospital admission was also apparent in one other study [7]. Nonetheless, other authors concluded that general anaesthesia [9, 11, 12], regional anaesthesia [9, 11], subarachnoid block with deep sedation [13], and even monitored anaesthesia care [9], affected admission. These discrepancies may indicate distinct drugs or routes of administration. Moreover, the same studies did not investigate other variables, like pain [9, 12], nausea and vomiting [9, 11], or haemorrhage [9, 13] which could confound the aforementioned associations. Besides, we could argue that studying the type of anaesthesia lacked benefit because it would always be dependent on the type of surgery.

Our study revealed that post-operative nausea and vomiting (PONV) influences hospital

admission. Others had similar conclusions [7, 12, 13]. The incidence of PONV in our study

(2.0%) reflects a routine anti-emetic prophylaxis protocol at our DSU since July 2001. The proportion of admissions attributed to PONV were 7.2% in this study, and 6% [9], 7% [11], 14% [7] and 18% [12], in other studies.

Severe post-operative pain also increased the likelihood of admission in the present study. Fortier et al [7], despite referring to pain as a predictive factor, did not mention its intensity. The major influence of the duration of anaesthesia on admission, as we found in our study, compares favorably with the effect of the duration of surgery [7, 9, 11, 13] or the time in the operating room [12], of other authors. These distinct times probably relate to the same phenomenon: extension of surgery. Nevertheless, only a multivariate comparison between them could determine whether more than one had an independent nature.

Gynaecology was shown to be a predictive factor in our study. The logistic regression model allows us to conclude that this effect is independent of other variables studied, i.e., it cannot be attributed, for example, to haemorrhage, nausea and vomiting, or pain. The reasons why gynaecology could have had this effect may include a greater rate of conversion from laparoscopy to laparotomy, surgical team characteristics, or previous abdominal surgery [8].

None of these variables were investigated. Additional studies are necessary to explain this finding.

Others have found urology to be a predictive factor [7, 11, 12], and related the fact to a greater incidence of haemorrhage or urinary retention. Only Fortier et al [7] simultaneously studied haemorrhage. Otorhinolaryngology has also been mentioned as a risk factor [7] but we did not study this variable, as we do not have this speciality in our DSU. Linares et al [13] mentioned procto-perineal-sacrococcygeal procedures (without studying haemorrhage), and Gold et al [12] also considered lower abdominal surgery and laparoscopy as predictive factors.

According to Fancourt-Smith et al [10], one possible explanation why a surgical speciality might influence hospital admission, relates to the proportion of diagnostic procedures performed by that speciality in the DSU. Findings at those diagnostic procedures could justify admission. After reviewing the causes for admission in our study, we did not find evidence supporting this hypothesis. Hedayati and Fear [14] investigated predictive factors for admission in laparoscopic gynaecological surgery. They mentioned a greater likelihood of

Table 5 Univariate analysis.

	Patients			
Factor	**Total number (n=6740)**	**Admitted (n=55)**		
		Number	**%**	**P Value**
Gender				0.09
Male	2963	18	(0.6)	
Female	3777	37	(1.0)	
Age (years)				0.06
≤ 20	754	1	(0.1)	
21-40	2563	19	(0.7)	
41-60	2490	23	(0.9)	
> 60	933	12	(1.3)	
ASA				0.21
1	3107	19	(0.6)	
2	3028	28	(0.9)	
3	501	6	(1.2)	
4	104	2	(1.9)	
Anaesthesia				0.04
General	3807	40	(1.0)	
Regional	603	1	(0.2)	
General and regional	1267	10	(0.8)	
Sedation with local	1063	4	(0.4)	
Speciality				< 0.001
General surgery	3077	15	(0.5)	
Vascular surgery	924	15	(1.6)	
Gynaecology	808	15	(1.8)	
Urology	558	5	(0.9)	
Others*	1373	5	(0.4)	
Anaesthesia duration (min)				< 0.001
< 60	4854	15	(0.3)	
60-120	1682	25	(1.5)	
121-180	179	8	(4.5)	
> 180	25	7	(28.0)	
Pain				< 0.001
Mild	6167	40	(0.6)	
Moderate	560	13	(2.3)	
Severe	13	2	(15.4)	
Nausea and vomiting				< 0.001
No	6604	47	(0.7)	
Yes	136	8	(5.9)	
Haemorrhage				< 0.001
No	6646	37	(0.6)	
Yes	94	18	(19.1)	
Anaesthesia consultation				0.05
No	2967	17	(0.6)	
Yes	3773	38	(1.0)	

*Dermatology, neurosurgery, neuropathology and orthopaedics. Corresponding total patients/patients admitted (%): 6/0 (0.0); 149/5 (3.4); 256/0 (0.0) and 962/0 (0.0), respectively.

Table 6 Logistic regression – multivariate analysis.

	Odds ratio	
Factor	**(95% confidence interval)**	**P value**
Speciality		
Others	1.0	
Gynaecology	12.0 (5.3 - 27.1)	< 0.001
Nausea and vomiting		
No	1.0	
Yes	6.3 (2.4 - 16.1)	< 0.001
Haemorrhage		
No	1.0	
Yes	42.6 (20.9 - 86.7)	< 0.001
Pain		
Mild	1.0	
Moderate	2.1 (1.0 - 4.5)	0.05
Severe	13.6 (1.6 - 115.2)	0.01
Anaesthesia duration		
< 60	1.0	
60 – 120	7.6 (3.3 - 17.8)	< 0.001
121 – 180	25.3 (8.2 - 78.0)	< 0.001
> 180	279.7 (74.4 - 1052.0)	< 0.001
Anaesthesia technique*		
Others	1.0	
General	1.0 (0.5 - 2.0)	0.99

*General anaesthesia (except combined anaesthesia) versus all others (combined, regional, sedation with local).

admission for laparoscopic tubal ligation compared to diagnostic laparoscopy. Mingus et al [9] did not find any association between surgical speciality and hospital admission. Haemorrhage was the most common cause for admission, as in other studies [7, 11], and also a major predictive factor as in the study by Fortier et al [7].

Conclusions

The most important predictive factors for hospital admission are surgical. Therefore, the type of procedure and surgeon's experience are crucial to avoid unplanned admission.

Given that the duration of anaesthesia influences hospital admission, scheduling potentially lengthy procedures as inpatients could decrease the unplanned hospital admission rate. Control over pain and PONV increases the efficacy of an ambulatory surgery programme.

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Ambulatory anaesthesia in the Netherlands: a survey of practise

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Abstract

We conducted a survey on anaesthesia practise for ambulatory surgery in The Netherlands with the purpose of identifying patterns and comparing them to published recommendations. Overall response rate was 69%. 97% of Dutch hospitals have ambulatory wards and 25% have dedicated operating rooms. Preoperative anxiolytic use is relatively high, approximately 40%. Prophylactic anti-emetic use is low, 33% for laparoscopic cholecystectomy, but a further 33% of patients require rescue treatment. Combination analgesic use is infrequent, with just one analgesic being used in more than 50% of patients. There is a strong preference for both locoregional, 85% for upper limb surgery, and neuroaxial techniques, 65% for lower limb surgery. However, use of continuous peripheral nerve block catheters for pain control following discharge is limited. We conclude that closer adherence to guidelines on PONV prophylaxis and greater use of multimodal approaches to pain management would be beneficial.

Keywords: survey, day case, anaesthesia, ambulatory, PONV, locoregional.

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Introduction

The past decade has seen an enormous increase in the both the number and type of procedures performed in the ambulatory setting. Vast improvements in the development of both anaesthetic and surgical techniques, allow a growing number of patients with poorer health status to have more complex procedures performed on an ambulatory basis [1, 2].

Despite an increasing amount of research focusing on ambulatory anaesthesia techniques, there are few publications reporting everyday patterns of practise and how these relate to published recommendations. Indeed, earlier publications in individual countries have confirmed that wide variation in practise exists [3, 4]. Thus, the purpose of this survey was to record variations in ambulatory anesthesia practise in the Netherlands and compare the findings to published evidence, highlighting potential areas for development.

Methods

Following local ethics committee guidelines, we designed a structured questionnaire consisting of a series of closed questions concerning various aspects of ambulatory anaesthesia practise. (See Appendix 1). A number of questions were based on similar previous surveys in other countries [4, 5].

The survey was posted to the 101 hospitals throughout The Netherlands, with a cover letter requesting that the questionnaire be completed by the anaesthesia consultant with main responsibility for ambulatory practise.

Four specific types of surgery were listed i.e. Dupytren's release (plastic surgery), knee arthroscopy (orthopaedic surgery), laparoscopic cholecystectomy (general surgery) and paediatric circumcision (paediatric surgery). Dupytren's release and knee arthroscopy were choosen as they are relatively frequent in the ambulatory setting. Paediatric circumcision was choosen as representative of paediatric ambulatory practise. Laparoscopic cholecystectomy was included as it is an emerging procedure in our ambulatory practice, presenting new challenges in terms of analgesic control and PONV prevention. The survey questions covered the following areas; general information on ambulatory unit set up, premedication, anti-emetics, induction and maintenance drugs, airway management, analgesic drugs and locoregional/neuroaxial techniques.

Where hospitals indicated that they did not perform a particular type of surgical procedure, then only those who did perform it were used for calculations. In the event that answers were illegible, results were discarded and calculations based on the total minus these discarded answers. Where more than one response was given in situations requiring a single response, the response was weighted by the number of responses offered.

Results

General information

71 of the 101 quesionnaires were returned. Two had not been completed, giving an overall survey response rate of just over 69%. 25% of respondents stated that their hospital had dedicated ambulatory operating rooms (n=69) and 97% of respondents stated that their hospital had dedicated ambulatory wards (n=69). Distribution of day case patients based on ASA classification was as follows; ASA 1: 62%, ASA 2: 31%, ASA 3: 7.3% (n=62). Concerning specialities working in ambulatory practise; plastic surgery made up 11%, orthopaedic surgery 31%, general surgery 27% and paediatric surgery 21% of the total ambulatory surgical procedures in the hospitals that responded. The average duration of a day case surgical procedure was 39 minutes (95% CI: 35.5- 43.08 minutes, n=57).

Use of anxiolytic premedication

Anxiolytics were administered as follows; 39% for Dupytren's release (n=56), 41% knee arthroscopy (n=61), 37% laparoscopic cholecystectomy (n=54) and 24% for paediatric circumcision patients (n=55). Distribution of anaesthesia techniques used for each procedure is listed in Table 1.

Table 1 Anaesthesia technique.

Anaesthetic technique	Dupuytren's release (n=68)	Knee arthroscopy (n=68)	Laparoscopic cholecystectomy (n=60)	Paediatric circumcision (n=67)
GA	16	20	98	18
RA	82	15	0	0
NA	0	64	0	<1
GA-RA	1	<1	<1	64
GA-NA	< 1	<1	<1	17

n is number of completed responses. Values are percentage of respondents. GA = general anaesthesia, RA = regional anaesthesia, NA = neuroaxial anaesthesia, GA-RA= combination of general and regional anaesthesia, GA-NA = combination of general and neuroaxial anaesthesia

Use of anti-emetic premedication.

The most frequently used anti-emetics in Dutch ambulatory practise are 5H3 antagonists (granisetron and ondansetron), metoclopramide and dexamethasone. Antiemetic use by procedure is found in Figure 1. Other PONV-limiting techniques used include; avoiding N2O (61/69), TIVA (60/69), no opioids (7/69), others (24/69) e.g. opting for regional anaesthesia blocks.

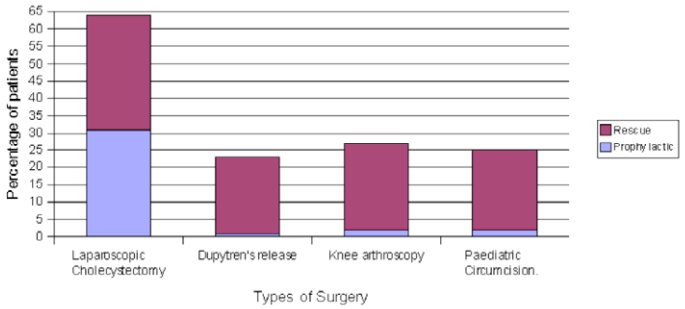

Figure 1 Anti-emetic use for the procedures listed. Total height of bar is percentage of patients who receive either prophylactic or rescue anti-emetics.

Named anesthetic agents and airway devices used are found in Tables 2 and 3, respectively.

Muscle relaxants

Muscle relaxants are used for laparoscopic cholecystectomy in 90% of cases (n=57), knee arthroscopy 11% (n=67), Dupytren's release 6% (n=64) and paediatric circumcision 1% (n=66). The 2 most commonly used muscle relaxants are rocuronium (43%) and mivacurium (38%). The percentage of cases rountinely utilizing suxamethonium is 2% in adults and 4% in paediatrics.

Table 2 Named anaesthesia induction & maintenance agents.

Agent	Adult (n=173)	Paediatric (n=64)
Propofol (I)	90	24
Sevoflurane (I)	2	73
Etomidate (I)	3	2
Midazolam(I)	2	1
Thiopentone (I)	2	0
Halothane (I)	0	0
Ketamine (I)	0	0
Other (I)	1	0
Sevoflurane (M)	61	95
Propofol (M)	33	5
Isoflurane(M)	3	0
Desflurane (M)	2	0
Enflurane (M)	0	0
Halothane(M)	0	0
Other (M)	1	0

n is number of completed responses.
Values are percentages. I = induction, M = maintenance.

Analgesics

Short acting opioids are the most frequently used analgesics with sufentanil being the most popular. The use of the NSAID, diclofenac is low, at just 8% and 7% respectively for Dupytren's release and knee arthroscopy. Full results are given in Table 4.

Table 3 Airway devices used.

	Dupytren's release (n=56)	Knee arthroscopy (n=63)	Laparoscopic cholecystectomy (n=56)	Paediatric circumcision (n=65)
LMA	92	96	96	71
ETT	3	2	2	2
Face mask	3	2	2	27
Other	2	0	0	0

Table 4 Named analgesics and number of combined analgesic.

Named analgesics/ combination analgesics	Dupytren's release (n=62)	Knee arthroscopy (n=68)	Laparoscopic cholecystectomy (n=57)	Paediatric circumcision (n=65)
None given	3	0.5	0	12
Alfentanyl	19	16	5	18
Diclofenac	8	7	5	5
Fentanyl	17	19	16	23
Morphine	2	2	4	3
Piritamide	0	0.5	3	1
Remifentanil	10	8	22	3
Sufentanil	38	43	44	33
Other	3	4	1	2
1 analgesic	58	62	53	71
2 analgesics	23	27.5	25	15
3 analgesics	8	7	9	3
4 analgesics	5	3	7	3
5 analgesics	3	0	4	0
6 analgesics	0	1	2	0
No analgesic	3	0.5	0	8

n is number of completed responses. Values are percentages.

Regional techniques

Locoregional blocks are most frequently performed in the holding area/reception (68%), followed by 21% in the operating room and the remaining 11% in the anaesthesia induction room. The most commonly used blocks for Dupytren's release are axillary block (35%) and Bier's block (34%) (n=67). Other upper limb blocks that were used include vertebral infraclavicular block (VIB) 26%, wrist 2%, interscalene 2%, elbow <0.5% and PIPA <0.5%.

Just 12 centres performed knee arthroscopy under locoregional anaesthesia. The most common block was a combined femoral/ sciatic (70%), followed by sciatic/psoas (25%). Penile blocks are administered for children undergoing circumcision in 62% of cases (n=67). The most popular local anaesthetics for regional blocks are listed in table 5. Additives are not combined with local anaesthetic agents for locoregional techniques in 49 of the centres that responded. The remaining centers use one or more additives, most commonly, adrenaline (n=20) and opioids (n= 10), with clonidine and bicarbonate use in just 5 and 1 centre respectively.

Neuroaxial blocks

Where a neuroaxial technique is used for knee arthroscopy, it is most commonly a spinal (66/68). In 2 of 68 centres, a combined spinal/epidural technique is used. Neuroaxial techniques are occasionally used for laparoscopic cholecystectomies with 5 of the responding centres using spinals and 4 using epidurals. For paediatric circumcision, caudal anaesthesia is used in 42 of the 45 centres which responded. Local anaesthetic agents for neuroaxial techniques are listed in table 5. 48 of the responding centres do not use additives to local anaesthetic drugs for spinal anesthesia. Continuous peripheral nerve blockade is offered by 2 of the 69 ambulatory surgery centres that responded.

Table 5 Named local anaesthetic agents for locoregional and neuroaxial anaesthesia blocks..

Local anaesthetic agent	Locoregional techniques (n=69)	Neuroaxial techniques (n=68)
Lidocaine	23	36
Bupivcaine	23	27
Ropivacaine	20	4
Mepivacaine	15	4
Prilocaine	13	7
Levobupivacaine	3	4
Other	3	18

n is number of completed responses. Values are percentages.

Discussion

To our knowledge this is the first national survey in the Netherlands looking specifically at aspects of ambulatory anaesthesia practise. The purpose of the survey was to identify current practise and compare the findings with published evidence. A response rate of 69% was achieved. This response rate is similar to previous studies in other countries [3, 4, 5].

97% of Dutch hospitals have dedicated ambulatory wards, an important factor for ensuring efficient pre- and pos -operative patient review. Interestingly, only a quarter of responding Dutch hospitals have dedicated ambulatory operating rooms. This is a low figure, considering the contribution which logistics and organizational

factors make to the successful running of such units. It is widely recognised that mixed inpatient and day case lists do not achieve the same level of care as dedicated day case lists [6]. Another advantage of a dedicated pracice is the availability of specialized staff with an interest in developing and advancing techniques.

An interesting finding is the frequent use of anxiolytic premedication, administered to approximately 40% of adult patients and almost 25% of paediatric patients, compared to just 12% of orthopaedic patients and 6% of urology patients in the UK in 2000 [4]. While this may be related to cultural differences, it does suggest a need for more optimal psychological preparation of patients within the Dutch system. It must however be noted that, a reluctance to offer anxiolytic premedication on the basis that it may delay patient discharge has not as yet been supported by the literature [7].

One of the most important findings in this survey is the large percentage of patients who require rescue or treatment anti-emetics (Figure 1), 33% for laparoscopic cholecystectomy and approximately 25% for each of the other procedures listed. This clearly demonstrates that a significantly greater number of patients would benefit from prophylactic administration of anti-emetic medication. Given that PONV continues to be one of the biggest challenges in modern anaesthesia practise, with an incidence as high as 70% in certain high-risk patients [8], closer adherence to prophylactic anti-emetic administration guidelines is indicated. In addition to delaying patient discharge and increasing costs, PONV contributes to low patient satisfaction scores [9]. The optimal cost-effective approach to the management of PONV differs between an ambulatory and an inpatient setting [11]. Anti-emetics should be administered to those with a moderate to high risk of PONV; a combination of a 5-HT3-antagonist and one other agent such as dexamethasone is probably the best combination available at this time [11,12]. Other potential PONV reducing maneuvers may include avoidance of N20, adequate hydration and use of locoregional techniques.

Regarding airway management, the LMA is not surprisingly extremly popular, used in more than 90% of cases. A possible emerging trend is the use of the LMA for laparoscopic cholecystectomy, in this survey reported in 2% of cases. Recent publications have reported the safe use of LMAproseal devices, as an alternative to the ETT in carefully selected patients undergoing laparoscopic procedures [13, 14].

Analysis of pain management displays some key points. Firstly, the short acting opioids have largely replaced the longer acting opioids. Remifentanil, with its rapid elimination profile, is now used in 20% of centres. Most surprisingly, combination use of analgesic drugs is limited (Table 4). Only approximately one fifth of centres combine 3 or more analgesics in patients undergoing laparoscopic cholecystectomy. Given the known syngeristic effects of certain analgesic combinations [15], this highlights a significant under-use of an important tool in pain management.

This survey confirms the popularity of locoregional techniques within the Dutch system. Such techniques have been shown to provide competitive discharge times, prolonged analgesia and reduced requirement for opioids [16,17,18]. An additional advantage is that more rapid patient 12 turnover can be achieved when blocks are performed outside the operating room [19]. The use of longer acting agents in the home setting has not been shown to increase risk [20, 21] and ropivicaine is now used in 20% of Dutch centres. However, the number of hospitals offering continuous peripheral nerve blockade catheters is currently very limited. Such techniques have been shown to provide safe and effective analgesia following ambulatory surgery [16, 21, 22] and allow more complex and painful procedures to be performed in the ambulatory setting.

Despite known disadvantages, including urinary retention and the risk of developing transient neurological symptoms (TNS) [24], neuroaxial techniques are popular among the units surveyed. Selective spinal anesthesia (SSA), using minimal doses of intrathecal agents may be a useful option[26].

In conclusion, this survey provides interesting data on ambulatory anesthesia practise within the Netherlands, although we believe that many of the trends may be applied to ambulatory practise particularly within other European countries. The main findings include a clear recognition of the benefits of the newer anaesthesia agents in combination with LMAs. A multimodal approach is used in the prevention of PONV, but closer adherence to recommended guidelines for prophylactic administration of anti-emetics is indicated. Finally, in terms of pain management there is clear room for further expansion of the role of analgesic combinations and continuous peripheral nerve block catheters.

Acknowlegements

The authors wish to sincerely thank all the consultant anaesthetists who took the time to complete and returns the survey questionnaires.

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An audit of compliance with national and local guidelines for day case cataract surgery at Aberdeen Royal Infirmary, Aberdeen

Dr. Ruby Pratap and Dr. Ann Robertson

Abstract

An audit was conducted in a Scottish teaching hospital to assess the level of adherence to local and national guidelines for day case cataract surgery under local anaesthesia. A questionnaire based on the guidelines was completed by the nursing staff for a period of eight weeks in locations performing day case cataract surgery in Aberdeen Royal Infirmary. We discovered that there were several areas where compliance with the guidelines was unsatisfactory. 23% of the patients had to wait longer than 3 months for their surgery from the time of pre-operative assessment. On the day of surgery, contrary to recommendations, 38% omitted their normal medication, 46% arrived fasted unnecessarily, 27% did not have their INR checked and 3% had diastolic blood pressure higher than 100mmHg. Based on these results a consultation exercise was undertaken and remedial measures put in place.

Keywords: Day case cataract surgery, Guidelines.

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Introduction

The introduction of phacoemulsification has permitted cataract surgery to be performed under local anaesthesia in patients with multiple co-morbidities. With this technique there is no need for anaesthetic personnel to be present in the operating theatre during the procedure. Under these circumstances, guidelines from the anaesthetic department would be particularly useful. Guidelines for the performance of day case cataract surgery were published in 2001 by the Royal College of Ophthalmologists and the Royal College of Anaesthetists [1]. This was soon followed by the publication of guidelines by Scottish Intercollegiate Guidelines Network (SIGN) [2]. Based on these guidelines a set of local guidelines were introduced in Aberdeen Royal Infirmary in 2001 and anaesthetic cover was reduced for day case cataract surgery. The local guidelines have not been audited since their implementation. A revised set of guidelines was subsequently published in 2004 by the Royal College of Ophthalmologists [3].

Aims and Objectives

1. The aim of the current audit was to identify the extent to which the local and national guidelines were being followed and to improve compliance if necessary.
2. To establish if the local guidelines needed to be revised in the light of more current and updated guidance.

Methodology

A prospective audit was carried out during the months of December 2004 and January 2005. A questionnaire based on the guidelines was distributed to the nursing staff on the ward and theatres, to be filled in by them on the day of surgery.

The following factors were analysed:

1. Waiting time between preoperative assessment and surgery.
2. Whether the routine medication was taken by the patient on the day of surgery.
3. Fasting status of the patient on the day of surgery.
4. For patients on warfarin (a) whether the INR was checked by the general practitioner and (b) whether surgery was cancelled if it was found to be high.
5. Patient's diastolic blood pressure on admission and whether the surgery was cancelled if it was found to be greater than 100 mm Hg.
6. Type of local anaesthetic technique used.
7. Establishment of venous access during surgery.

The data collected through the questionnaires were entered into an Access database and subsequently analysed.

Results

During the study period 175 day case cataract procedures were performed. Return rate of the questionnaires was 100% with some returns containing incomplete data. The results are shown below:

1. Time gap between pre-operative assessment and surgery: Data was available for 160 (91%) patients. The 90 day compliance was achieved in 124/160 (77%) patients.
2. Ingestion of normal medication by the patient on the day of surgery: 164 patients were on medication but only 101 took their medicine prior to arrival (62%).
3. Fasting status: 80 out of 175 patients (46%) arrived fasted on the day of the procedure
4. Warfarin: 11 patients were on warfarin. 7 patients had their INR checked by their general practitioner as recommended. In two of the above patients the INR was above 2 but surgery was not cancelled.
5. Diastolic blood pressure on admission: The diastolic blood pressure

was greater than 100 mm Hg in 5 out of 175 patients (3%). Surgery was not cancelled in any of these patients.

6. Local anaesthetic technique: Data was available for 168 out of 175 patients (96%). 140 patients (83%) received local anaesthetic eye drops, 25 patients (15%) were given sub-Tenon's injections and 3 patients (2%) were operated under peri/retrobulbar injections.
7. Venous access: Venflons were inserted in all patients in the retro/peribulbar group, 3/25 patients (12%) from the sub-Tenon's group and 16/140 patients (11%) undergoing surgery with local anaesthetic eye drops.

Discussion and Conclusions

Local and national guidelines drawn up to maintain a safe and efficient passage of the patient through the surgical journey were not adhered to completely in all domains. As per national guidelines the time gap between pre-op assessment and surgery should not be more than 90 days. The reasons for non compliance (23%) were not within the remit of the audit and need to be explored further.

Despite clear instructions at the pre assessment visit 38% patients did not take their usual medication on the day of surgery. Fasting is not required for day case cataract surgery under local anaesthetic. This audit showed that 46% of patients nonetheless arrived fasted for their procedure. The reasons for non compliance in this area could be related to the long time interval between pre-op assessment and surgery, patient's perception of the need to fast, and forgetfulness on the part of the patient.

When patients on warfarin are pre assessed, an information letter is sent to the General Practitioner. The patients are advised to get their INR checked from their GP practice 5 days prior to the proposed date of surgery. Despite these written instructions 27% of patients on warfarin did not have their INR checked. Contrary to local guidelines 2 patients with INR higher than 2 proceeded to have their surgery. It should be noted that the revised guidelines from the Royal College of Ophthalmologists (Ref 3; p 19) state that the INR is allowed to be in the desired therapeutic range. This changed recommendation needs to be incorporated into the local guidelines.

Local and national guidelines state that diastolic blood pressure should be <100 mm Hg. for the procedure to be carried out safely. There were 5 patients with diastolic blood pressure >100 mm Hg who proceeded to have their surgery performed.

With regard to venous access there is a discrepancy in the recommendations of the national and local guidelines. Local guidelines recommend the insertion of venflons in the peri and retrobulbar as well as in the sub-Tenon's group. This recommendation is related to the geographic isolation of the Day case theatre from the main theatre suite. The results of the present study show full compliance with the national guidelines. However contrary to the local guidelines, only 16% of the sub-Tenon's group had a venflon inserted. In the local anaesthetic eye drops group, 11% had venflons inserted even though it is not the recommended practice.

Recommendations

The reasons for the long delay between pre assessment and surgery will need to be identified and addressed. The information conveyed to the patients at the time of preassessment will require to be formalised in order to improve compliance and a detailed handout of instructions is recommended. A phone call on the day before surgery may prove to be useful. This might improve compliance with the normal medications and fasting status. The new guidelines proposed by The Royal College of Ophthalmologists [3] regarding Warfarin administration need to be incorporated into the local guidelines. The new guideline state that Warfarin need not be stopped as long as the INR is with in the therapeutic range. National guidelines recommend establishment of venous access only in the subgroup of patients undergoing the sharp needle technique, i.e.; peribulbar and retrobulbar group. The local guidelines need to be modified to reflect this recommendation.

This audit was presented to the ophthalmic department and all the recommendations have been taken on board. A re-audit will be performed after an appropriate time interval once the necessary changes have been put in place.

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Blood flow management in hand surgery using the S-MART™ device: a prospective randomized controlled study

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Abstract

Aim: Tourniquets are commonly used in ambulatory upper-limb surgery, but are still associated with complications, malfunction, and pain. We evaluated the S-MART™ device for blood-flow management compared to a conventional pneumatic tourniquet.

Methods: Sixty patients were assigned to study and control groups, where arterial occlusion was achieved by S-MART™ device and pneumatic tourniquet, respectively.

Results: S-MART™ was safe, but more difficult to apply and caused more pain.

Conclusion: The S-MART™ proved to be a fast and safe tool, but induced a compression discomfort. The costs of using this disposable product should be contemplated when considering its addition to day-care operating room armamentarium.

Keywords: Tourniquet, Esmarch, Exsanguination, Arterial occlusion, Hand, Carpal tunnel release, Evaluation, Pain, Complication.

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Introduction

Achieving a bloodless surgical field enhances the surgeon's capability to identify fine structures, shortens the duration of anaesthesia and surgery, and minimizes intraoperative blood loss. In surgical procedures performed on the upper extremity, proper visualisation is crucial, and the pneumatic tourniquet is often an inherent element of the surgical landscape. Attaining a bloodless surgical field necessitates an exsanguination followed by arterial occlusion proximal to the surgical site. The former action is often achieved by using the Esmarch technique, while the latter is achieved by using a pneumatic tourniquet.

The use of the conventional pneumatic tourniquet is associated with morbidity [1] and rare mortality [2]. Despite the paucity of information regarding the incidence of individual complications, the rate of complications associated with using the pneumatic tourniquet is estimated as 0.013% to 1.15% [3]. Potential local complications include tourniquet failure causing inadequate hemostasis, skin trauma, muscular and neuro-vascular injuries, wound infection, wound hematoma, edema, and compartment syndrome. Local discomfort or pain may increase steadily until becoming unbearable. Systemic complications include volume overload, arterial hypertension, cerebral infarction, rhabdomyolysis, pulmonary embolism, and metabolic disturbances [1,3].

Conventional exsanguination using the Esmarch technique is performed by tightly wrapping a rubber band around the limb, and thereby propelling the blood proximally. The surgeon has no quantitative indication on the pressure applied to the patient's limb, and therefore, local complications are mostly related to the uncontrolled excessive pressures generated (pressures in excess of 1000mmHg have been reported). The twisting, compressive, and shearing forces generated jeopardize the skin and soft tissue integrity. Severe systemic complications including fatal pulmonary embolism have been reported [4]. Furthermore, pneumatic tourniquets are prone to various operational problems, and their technical reliability and consistency are limited. Regular maintenance is essential. Still, technical failure due to malfunctioning components causing air leakage, pressure drop, and inadvertent excessive pressure are unavoidable.

The various techniques for exsanguination have limited reliability and reproducibility. Studies on changes in local blood volumes in limbs based on either plethysmographic or scintigraphic methods [5] showed that the effectiveness of the ordinary exsanguination techniques is limited. Blond et al [6] used a Gamma camera to assess the reduction in regional blood volume in upper limbs of healthy male volunteers given an autologous injection of 99mTc-labeled erythrocytes. They evaluated the effectiveness of different exsanguination techniques. The median percentage reductions of blood volume ranged between 42% when hand-over technique was used and 69% when the Esmarch technique was used. Comparable reduction rates were measured in lower limb exsanguinations [7].

Many surgical procedures on the upper limb are performed under local anaesthesia. The patient, therefore, experiences some level of discomfort or pain induced by the compressive forces applied by the pneumatic cuff. This may subjectively range from an unpleasant experience to unbearable pain, which frequently causes patient restlessness and occasionally requires discontinuation of surgery. In an attempt to decrease this discomfort, investigators have suggested various technical and ergonomic modifications, including alterations in the inflation pressure, shape, dimensions, design and location of the tourniquet [8–10].

The S-MART™ device (OHK Medical Devices – a division of Oneg HaKarmel Ltd., Haifa, Israel) was designed to achieve a combination of exsanguination, arterial flow occlusion and a sterile surgical field. The device is listed by the United States Food and Drug Administration and certified by the Israeli Ministry of Health. Boiko and Roffman [11] have published their clinical experience in using this device in upper limb surgery. They reported a quick device application and removal, and the achievement of an excellent bloodless field. Our prospective, randomized, and controlled study aimed at comparing the S-MART™ to the standard upper-arm pneumatic tourniquet,

regarding efficiency and potential adverse effects, including quantitative assessment of induced pain.

Patients and Methods

The S-MART™

The S-MART™ (OHK Medical Devices – Division of Oneg HaKarmel Ltd., Haifa, Israel) is composed of an elastic silicon ring with an inner diameter of 52mm and outer diameter of 76mm, wrapped in an elastic tubular stockinette sleeve and two straps, each ending in a pull handle (Fig. 1)

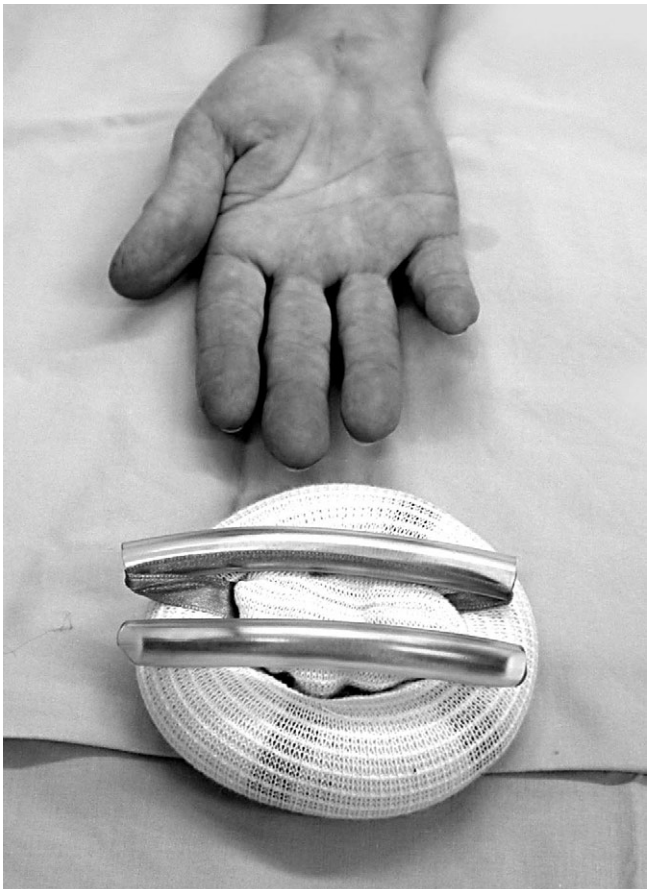

Figure 1 The S-MART™ device.

The device is provided sterile and double-packaged. It is applied to the limb after skin preparation and draping by placing the ring on the fingertips, and then pulling on both handles proximally (Fig. 2).

Figure 2 The surgeon places the ring on the fingertips and then pulls the two straps proximally.

As the ring rolls proximally it exerts a supra-systolic pressure wave upon the limb, which both exsanguinates the limb by propelling the blood proximally and occludes the arterial flow at the level of device positioning. While rolling the ring, the stockinette unfolds onto the limb, covering it up to the occlusion location, thus placing a sterile covering (Fig. 3).

Figure 3 The silicone ring rolls up the limb and the stockinette unfolds onto the forearm during the motion.

This covering is incised to gain access to the surgical field. For carpal tunnel release we placed the device at the junction of the upper and middle thirds of forearm, where an adequate mass of soft tissue interposes between the elastic ring and bony structures. We used the S-MART™ designed for the upper limb, which is provided in three color-coded models, each designated to apply the appropriate occlusion pressure for different ranges of systolic blood pressure, covering the range of systolic blood pressure up to 180mmHg. The pressure created is supra-systolic and ranges between 250mmHg-350mmHg in limbs with a circumference between 24cm and 40cm.

Patients

Sixty patients scheduled for elective open carpal tunnel release in an outpatient setting for idiopathic primary carpal tunnel syndrome were enrolled in the study. We included patients who were 18–85 years of age and whose circumference at the occlusion site was between 24cm and 40cm. We excluded patients with a systolic blood pressure in excess of 180mmHg, and patients with congestive heart failure or chronic vascular disorders. Other exclusion criteria were clinical evidence or history of deep vein thrombosis, clinical evidence for instability of bones or joints, and infection in the limb. The S-MART device is approved and certified by the Medical Devices Department of the Israeli Ministry of Health for clinical use. All patients were provided thorough information regarding the device prior to enrolling them in the study group. The open carpal tunnel release was performed under local anaesthesia (local infiltration/ injection of 5-10ml of lidocaine 2%), by three hand surgeons.

Study Protocol

The patients were randomly assigned to one of two groups: The study group (n=30) and the control group (n=30). Blood pressure (systolic and diastolic) was measured and mean blood pressure was calculated immediately before the application of the tourniquet. Patients in the study group had the exsanguination and the arterial occlusion achieved by the S-MART™ using the appropriate model as dictated by the systolic blood pressure. The device was placed at the junction of upper and middle thirds of the forearm after skin preparation and draping. An inflatable cuff was placed at the mid-arm to be inflated in cases that the S-MART™ failed or had to be abandoned. When surgery was concluded, the device was released by cutting the silicone ring and the stockinette sleeve after protecting the skin beneath with a blunt blade, and haemostasis was then undertaken and skin sutured.

In the control group a pneumatic tourniquet was used (Tourniquet 2500, VBM medizintecknik, GmbH, Sulzan, Germany). The apparatus consisted of an inflatable cuff (fabric single cuff, width – 7cm) inflated with compressed air, a pressure regulator, display and connecting tubing. The cuff was adequately padded and positioned at mid-arm. After skin preparation, draping and infiltrating the local anaesthetic agent, exsanguination was achieved by exerting external compression using an elastic bandage wrapped around the limb from fingertips up to the draped elbow, then the cuff was inflated up to a pressure of 250mmHg, the bandage unwrapped, and the surgery commenced. At the end of the surgery, the cuff was deflated, haemostasis was performed and the skin sutured. Failure of the S-MART™ or the pneumatic tourniquet was defined as poor visual quality due to an unacceptable bleeding at the surgical field, mechanical failure of the device, or patient's intolerance to pain caused by the device.

Evaluation

All patients were inquired regarding coexistent diseases and disorders including bleeding diatheses and coagulopathies, medications including analgesics (consumed within 4 hours before surgery). All relevant details were recorded in a report form for every case in both groups. The form was completed by the surgeon and included the time needed for placing the device (both exsanguination and arterial occlusion), technical difficulty in applying the device and cutting a window for the surgical site (ranked as simple, moderate, or difficult), the absence of radial and ulnar pulse and capillary filling, and the efficiency in providing a bloodless field rated from 1 (poor) to 5 (excellent). In cases where the efficiency was insufficient the blood pressure was measured and recorded. The surgeon quantified the bleeding at the surgical field either by milliliters of blood or the number of blood soaked gauzes. The surgeon also ranked the restlessness of the patient, measured the time to remove the device and ranked the difficulty in removing it, verified the resumption of arterial flow, and ranked his own overall satisfaction of the device. The duration of surgery from skin incision to wound closure was recorded as well (time needed for the application of the occlusion devices was excluded).

The patient was interrogated after the operation whether he experienced pain or inconvenience at the site of the device placement, and he had to rank this experience according to the "Visual Analogue Scale" for pain intensity – V.A.S. from 1 - "haven't experienced any pain" to 10 - "experienced intolerable pain". Failure of the device in each of the groups was declared when its use had to be discontinued, either because of ineffectiveness in securing an adequately bloodless field, inducing unbearable pain, or causing unacceptable adverse effect.

The limb was evaluated immediately after surgery and at a follow-up visit a week later, seeking local signs, and performing a complete neuro-vascular examination.

Statistical Analysis

Results were tabulated and expressed as means ±SD and ranges. Results were evaluated with unpaired two-tailed Student's t-tests, two-tailed chi-square tests, and F-test in order to check statistical differences between the two groups. P value of less than 0.05 was considered statistically significant.

We used an intention-to-treat analysis. We considered patients to be in the group to which they were assigned (even if S-MART™ failed and was substituted by the pneumatic tourniquet), and the denominator for each group was all patients assigned to that group.

Results

We enrolled 60 patients at the Rambam Medical Center (Haifa, Israel), and Ha'emek Hospital (Afula, Israel). Thirty patients were assigned to each group. The characteristics of the patients in the two groups are detailed in Table 1.

Table 1 Characteristics of the patients in the two groups[a].

Characteristic	Study group (n=30)	Control group (n=30)	P Value
Sex – M/F	7/23	8/22	0.77
Age – Yr	56±11 Range [38–79]	53±14 Range [26–84]	0.3
Systolic blood pressure	139±22	141±24	0.68
Mean arterial pressure	98±14	97±16	0.86
Analgesics – Yes/No	5/25	1/29	0.085

a Plus-Minus values are mean ± SD. All values are two-tailed.

The clinical characteristics including diagnosis, surgical procedure, anaesthesia, sex ratio (male:female), age, systolic blood pressure, and mean arterial pressure were similar in the two groups. The proportion of patients who used oral analgesic drugs within 4 hours before surgery was significantly higher in the study group. The mean duration of surgery was significantly higher in the control group ($P<0.001$) (Table 2Nevertheless, the application of the pneumatic tourniquet was reported as simple and straightforward in all control cases, while the technical difficulty in 13 applying the S-MART™ was graded as moderate in half of study cases. The SMART ™ application time averaged 10.8sec, and showed a trend of getting shorter as the study progressed, while average removal time was 9.4sec (Table 2).

Table 2 Intra-operative measurements in the two groups[a].

Characteristic	Study group (n=30)	Control group (n=30)	P Value
Duration of surgery - min	15±5 Range [8-30]	19±3 Range [14-26]	<0.001
Time of application - sec	10.8±2.6		
Difficulty in application (Simple/Moderate/Difficult)	15/15/0	30/0/0	
Time to remove device	9.4±2.3		
Analgesics – Yes/No	5/25	1/29	0.085

a Plus-Minus values are mean ± SD. All values are two-tailed.

We planned to quantify any bleeding occurring in either group by measuring the volume of blood loss (ml) and counting the gauzes saturated with blood. However, both devices were overall excellent in providing a bloodless field. In one case in the study group – a

female with a blood pressure of 163/85 mmHg – a yellow model of the S-MART™ was used; after skin incision a continuous bleeding obscured the surgical field. Blood pressure was measured and found to be within the indicated limits for the yellow model. Measures for local haemostasis were unsuccessful, and consequently the S-MART™ was released four minutes after starting surgery owing to unacceptable visual quality. Exsanguination was redone using an elastic bandage, and the pre-installed pneumatic cuff was inflated to a pressure of 250mmHg. The operation was completed in a completely bloodless field. All but one patient in the control group had a bloodless field and an excellent visual quality. In a case of a male with a blood pressure of 102/68 mmHg, minor bleeding was observed and the surgical field was ranked at 4 (in a scale of five degrees). This apparently was due to venous congestion caused by inappropriate exsanguination. The visual quality, however, was acceptable and the operation proceeded uneventfully.

All patients in both groups reported local discomfort caused by the device. However, experiencing true pain was significantly higher in the study group (P=0.0062) (Table 3). The average V.A.S. grading was higher in the study group (P=0.05), while variability of the grading was similar in both groups. Two patients in the study group ranked their pain severity as 10 on the V.A.S.. One patient reported a severity of 10 at the end of operation, which lasted 15 min. The other patient reported a severity of 10 two minutes after applying the S-MART™. The device was consequently released and substituted by a pneumatic cuff, which the patient tolerated well throughout the rest of the operation. In both cases, the surgeon reported patient's restlessness, which was graded as "unacceptable" in the latter.

The overall surgeon's satisfaction was similar in both groups. Apart from local skin redness at the site of device placement, which was uniformly observed in all patients in both groups and completely disappeared a few minutes thereafter, no skin complications, neurovascular compromise, or any other adverse effects were encountered postoperatively.

Discussion

Surgical operations on the upper limb usually involve delicate structures. Optimizing the surgical arena and ensuring adequate sighting is therefore crucial. A bloodless surgical field is an essential prerequisite for high visual quality. Hand surgeries are sometimes undertaken under local anaesthesia, and the patient may, therefore, experience some discomfort or even a distressing pain caused by the compressive force applied by the tourniquet device.

Using pneumatic tourniquets as an effective means of achieving a bloodless field has become a common practice in hand surgery. However, the effectiveness of the pneumatic device is not absolute, it is associated with potential complications, occasional technical malfunctioning and local sensation of discomfort. The SMART ™ device is designed for performing three sequential functions of limb exsanguination, arterial blood flow occlusion and placement of sterile field covering. The centripetally oriented force generated by the silicon ring provide a circumferentially even and consistent supra-systolic pressure, that is independent of gas tubing, pressure regulation, and electric connections. The S-MART™ is therefore suitable for interventions undertaken at outpatient and clinic settings.

The S-MART™ can be applied to the upper arm, as well as to the forearm. By applying the device on the forearm in operations performed at distal parts of the limb, ischemia of a significant portion of the limb is spared, and the anticipated re-perfusion effect is diminished. The S-MART™ is sterile and its placement in proximity to the surgical field is possible, which further decreases the ischemic mass of tissue.

Since the S-MART™ is a sterile single-use product, the surgeon applies and removes it without the need for assistance of any non-sterile personnel. However, alternate inactivation and activation of the flow occlusion, for haemostatic purposes for example, is unfeasible. The problem of device contamination with the patient's blood and the potential for consequent cross-contamination is avoided as well. However, a comparative evaluation of the costs of using and maintaining the reusable standard tourniquets and the disposable S-MART™ is required.

Table 3 Outcome in the two groups[a].

Criterion	Study group (n=30)	Control group (n=30)	P Value
Failure of device - No. of cases	2 [b]	0	0.15
Quality of bloodless field: 1 (poor) to 5 (excellent)	4.86±0.73	4.96±0.18	0.47
Patient reported inconvenience- Yes/No	30/0	30/0	
Patient reported pain – Yes/No	15/15	25/5	0.0062
V.A.S. [c] - 1 to10	5.7±2.5	4.53±1.99	0.05 (F-test P=0.22)
Surgeon reported patient's restlessness – 1 (unacceptable) to 5 (excellent)	4.77±0.77	5±0	0.10
Local signs	30 (redness)	30 (redness)	Local signs
Overall surgeon's satisfaction – 1 to 5	4.87±0.73	4.97±0.18	0.47

[a] Plus-Minus values are means ± SD. All values are two-tailed.

[b] Failure was declared due to bleeding and unacceptable visual quality in one patient and due to intolerable pain with patient's restlessness in another.

[c] V.A.S. denotes Visual Analogue Scale. A pain severity scale: from 1 – No pain, to 10 – intolerable pain.

The average application time for the S-MART™ was found to be as short as 10.8 sec, though the application was graded as moderately difficult in half of the cases. This was explained by the difficulty in rolling the ring across the wider zone of the metacarpophalangeal joints. Application of the pneumatic tourniquet is multistage and involves padding, wrapping and fastening the cuff, connecting the tubes, exsanguination, adjusting and inflation. These actions are not done in continuity and, therefore, attempts at measuring the time needed for performing them were unsuccessful.

The S-MART™ effectively provided a bloodless field in al but one case. The bleeding in this case has probably occurred due to either inadequate exsanguination causing venous congestion, or stress-related blood pressure fluctuation before skin incision beyond the indicated range of the yellow model causing arterial leakage.

Although the proportion of patients who consumed analgesics before surgery was higher, and the mean surgical time was significantly shorter in the study group, still, significantly more patients experienced pain caused by the S-MART™ than the pneumatic cuff. The mean V.A.S. score was higher in the study group (P=0.05), while the two groups showed similar score variability. The S-MART™ failed in one case due to intolerable pain and the surgeon reported unacceptable patient restlessness.

One additional clinical issue was observed. Following the cutting of the stockinette, small cloth residues were scattered over the skin, and entered the surgical field thereafter. This may be avoided by soaking the stockinette with a sterile fluid. Alternatively, close-ended stockinette should be replaced by an open-ended hemmed stockinette that covers the limb distally up to the surgical site.

In summery, the S-MART™ device performed well in providing a bloodless surgical field in all but one operation of carpal tunnel release. In two cases it caused unbearable pain and had to be released in one. This well-designed ergonomic device proved to be a fast and safe tool for blood flow management. However, it induced a compression discomfort that ranged between local inconvenience and intolerable pain. The costs of using this disposable product versus the reusable pneumatic system should be contemplated when considering the addition of the S-MART™ to the operating room armamentarium.

Acknowledgement

OHK Medical Devices, Haifa, Israel supplied all S-MART™ devices used in the study group free of charge. The authors have received no financial benefits, and have no financial interest in the device.

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