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Editorial

Mark Skues, Editor-in-Chief

This final edition of 2019 has rather sad news as we report the recent death of Paul Jarrett, a Professor of Day Surgery from Kingston-on-Thames in the United Kingdom. As more mature members of the Association will remember, Paul was a founding member of both the British Association of Day Surgery and the International Association of Ambulatory Surgery, rising to Presidential status in both organisations and playing a key role in the development of both of them. It seems fitting that we allocate space for an obituary written by Tom Ogg, which will also be reproduced in the next edition of the Journal of One Day Surgery. I remember Paul as a highly focussed individual whose primary aim was the dissemination of Ambulatory Surgery practice and principles to all who would listen. I'm sure we will all greatly miss him.

The papers in this edition are an eclectic set, with an emphasis on paediatric anaesthesia. Cavalete and co-workers have reviewed satisfaction with paediatric pre-operative evaluation. In their hospital, the development of pre-operative walking clinics for paediatric ambulatory surgery is a new one, and the authors were keen to demonstrate potential benefits. They found an overall high satisfaction rate with such clinics, with parents believing they were more cost efficient and provided more information about the proposed procedure than they would otherwise have received.

Morais and his colleagues from Portugal have reviewed the management of ambulatory dental procedures in children with intellectual disability over a 10 year period to see whether there were differences in management compared with an inpatient cohort. They found (perhaps predictably) a higher rate of non-cooperation in airway assessment with higher Mallampati scores in the ambulatory cohort, and a subsequent higher rate of inhalational induction of anaesthesia. However, such children were successfully manged in the ambulatory surgery environment without complications when compared with an inpatient cohort.

An Indian study evaluates the differences between spinal ropivacaine and bupivacaine, both with additional fentanyl, 25µg, for lower limb surgery. Given the ongoing interest in intrathecal techniques for ambulatory surgery using more evanescent agents such as prilocaine or 2-chloroprocaine, this is an interesting paper, demonstrating a shorter motor and sensory block with ropivacaine compared with bupivacaine, though I suspect more anaesthetists would employ shorter acting local anaesthetic agents in their daily practice.

The fourth paper is a review of sentinel node lymph biopsy, evaluating potential short term morbidity in the daycase setting. The authors followed 303 patients from 2008 to 2017, evaluating potential post-operative complications, finding seroma formation the most common (14.9%), followed by wound infection, (2.6%) and haemorrhage (1.3%). Admission to hospital was needed for the latter two categories, but overall, the authors contend that the procedure was safe and effective for ambulatory care.

Finally, as we reach the end of another year that was highlighted by an exceptional international congress in Porto, it's time to mark your diary for the next European Congress to be held in Madrid on 19th–ß21st April next year. Further details will be available soon on the IAAS website, so reserve your study leave now. In the meantime, I wish you all a happy Christmas and a prosperous New Year.

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Mark Skues
Editor-in-Chief

OBITUARY

Professor P E M Jarrett MA MB BChir FRCS (1943–2019)

Dr Tom W Ogg Formerly Consultant Anaesthetist and Director of Day Surgery, Addenbrookes Hospital, Cambridge, UK, Past President BADS & IAAS

We have lost a champion of Day Surgery. Personally I have lost a dear friend and colleague. Paul graduated from Cambridge University (1966) and after medical and surgical appointments at St Thomas's Hospital, London he became Consultant in General and Vascular Surgery at Kingston Hospital (1977–2003). He was appointed Professor of Day Surgery and Acute Day Care at Kingston University and St. George's Hospital Medical School (1996–2017).

Paul Jarrett had a global following especially in the field of day surgery. His earlier work on day surgery for inguinal repair proved a classic. In 1989 he became a Founding Member of the British Association of Day Surgery (BADS) and was elected its first Chairman and a member of the editorial board of the Journal of One-Day Surgery. In 1995 he was a Founding Member of the International Association of Ambulatory Surgery, an organisation to which 30 countries were affiliated. Paul became the President of the IAAS (1997-99). In 1997 he became an Honorary Life Member of BADS and in 2013 he was elected an Honorary Member of IAAS.

Paul and I teamed up following a series of meetings on day surgery when we addressed such subjects as how to establish day units, how they should be administered and pointed to the need for education and research in the field. The surgical waiting list in England & Wales stood at over one million patients so could a planned programme of day surgery alter this situation? Together we agreed that a national Association of Day Surgery might be the answer but we were well aware of strong opposition to our plans. To make them work we decided to establish a Multidisciplinary Association and the first BADS Congress was held at the Royal Society of Medicine in London. The main lecture theatre was booked for 200 delegates but on the day a further 50 people attended. Immediately Paul and I decided that there was great interest in day surgery and that we should increase our efforts to impress the NHS, the Secretary of State for Health, the Department of Health and Sponsors for finances to spread the good word. As we all know BADS is now safely established at the Royal College of Surgeons England and BADS celebrated its 30 year Anniversary this year.

In the earlier years the BADS committee met regularly in London pubs, hotels and at Barnet Hospital, Postgraduate Centre. Meetings were never cancelled and despite the heavy workload involved our committee would probably all do the same again. It was fun, especially when hundreds of day units were established throughout the United Kingdom.

Throughout this hectic period, Paul was a busy general surgeon on regular emergency duties. However he became Editor of the Journal of Ambulatory Surgery and wrote over 80 publications. In addition he delivered 25 UK Guest Lectures and 45 Overseas Guest Lectures. Over the years he assisted in the organisation of 18 UK Congresses and 13 International Conferences. What energy! His new Kingston Hospital Day Unit welcomed visitors from 23 different countries and of course they always invited Paul to spread the gospel at their own national meetings.

Paul also had a life outside of medicine, he served on the Boards of a number of public and private companies both national and international. He was a founder trustee of a local hospice. Few people will be aware that he was elected as a Freeman of the Company of Arts Scholars, Dealers and Collectors. In addition he held the office of Master of the Worshipful Company of Clockmakers (London).

Paul Jarrett was my friend. He was an enthusiast with abundant energy, a natural leader, an outstanding lecturer, a talented organiser. He was a very sociable person and lived life to the full. Our condolences go to Annie his dear wife and to his son Michael, a Consultant Surgeon at Kingston upon Thames.

Paediatric WalkIng Clinic – is it the future for ambulatory surgery?

S. Cavalete, C. Vieira, A.P. Silva, S. Pé D'arca

Abstract

Background/Purpose: Walking Clinic (WIC) is an innovative concept that consists of a step-by-step preoperative evaluation performed in a single visit. Our aim is to evaluate patient satisfaction in the paediatric population.

Methods: Evaluation of satisfaction levels and potential benefits through an anonymous questionnaire for one month.

Results: All patient's parents were satisfied with this modality resulting in numerous benefits including inferior costs for the parents, less absenteeism and better information about the ambulatory surgery.

Discussion: These results are consistent with the existing evidence for the adult population and support further research in order to widespread this innovative practice to paediatric population worldwide.

Keywords: Paediatric Ambulatory Surgery, Single Preoperative Visit.

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Introduction

Ambulatory Surgery is an integral part of surgery departments worldwide and accounts for more than 50% of all surgeries in many countries in North America, Europe, and Oceania [1]. It is a nearly perfect example of efficiency and quality in the treatment of surgical patients [2,3] and has numerous clinical, social and economical advantages contributing to patient safety and satisfaction.

In the paediatric population, daytime surgery has significant advantages allowing the child to spend less time away from their home environment while providing a quicker return to their daily activities, always guaranteeing their safety and a support network for any postoperative complication that may arise [4].

Despite the evolution and optimization of ambulatory surgery, pre-operative assessment still requires multiple visits to the hospital, before the patient is fit for surgery. This includes surgical and anesthesia consultations, patient education by a nurse and any complementary diagnostic studies deemed necessary. In the paediatric population this requires the child's absence from school but also the parent's absence from work.

In our institution all adult day surgery patients have been evaluated at a WalkIng Clinic (WIC) since March 2012 [2]. It consists of a pre-surgery clinical appointment with the surgeon, the anaesthesiologist and a nurse where all the pre-operative work-up, medical, social and psychological preparation can be made in a single visit [2,3]. The patients' response has been outstanding with increased satisfaction, reduced costs for the institution and for the patient [3].

From July 2016 we proposed that paediatric ambulatory surgery patients start being evaluated in the WIC. The circuit was the same as the adults, although with a much smaller population since paediatric surgical specialties are limited in our institution. Nonetheless, considering the positive aspects of the WIC in adults, our aim is to ascertain if this organizational change has advantages in terms of satisfaction, costs and other relevant issues to the children and their parents.

Methods

To understand if this change was relevant to the patients, the authors developed a written questionnaire which was delivered to the parents and answered by them at the end of the appointments. This was applied during a period of 1 month and it was filled out by the adult accompanying the child. Verbal and written consent was obtained before distribution of the questionnaire.

The questions covered demographic variables, who was accompanying the child and the surgical specialty. It then determined and scored the patient's satisfaction in 4 degrees (1 - Unsatisfied; 2 - Slightly Satisfied; 3- Moderately Satisfied; 4 - Completely Satisfied). Finally, there were a few subjective questions relative to gains in one single visit which include time, absence from work and financial savings.

The results were processed and analysed in SPSS Statistics® Version 23. Categorical variables are presented as frequencies and percentages, and continuous variables as means and standard deviations, or medians and interquartile ranges for variables with skewed distribution. Normal distribution was checked using Shapiro-Wilk and Kolmogorov-Smirnov tests or skewness and kurtosis.

Results

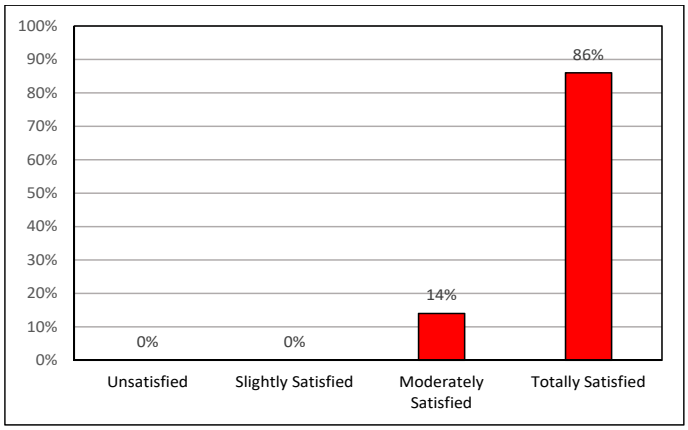
A total of 38 patients were evaluated in the WIC for this period. One was excluded because he didn't fill out the questionnaire. There were more female patients and the average age was 8 ± 4 years old. Demographic data is shown in Table 1.

Table 1 Demographic Data (Number and Percent)

Age in years ±SD	**8 ± 4**	
Gender	Male	16 (43.2%)
	Female	21 (56.8%)
Relationship	Mother	27 (73%)
	Father	8 (21.6%)
	Grandparent	2 (5.4%)
Surgical Specialty	ENT Surgery	26 (70.3%)
	Ophthalmologic Surgery	1 (2.7%)
	Orthopaedic Surgery	10 (27%)

All parents considered a single visit beneficial over multiple visits for the various preoperative appointments. Overall parent's satisfaction scores were positive with 86.5% being totally satisfied (Figure 1).

Figure 1 Satisfaction Scores regarding WIC.

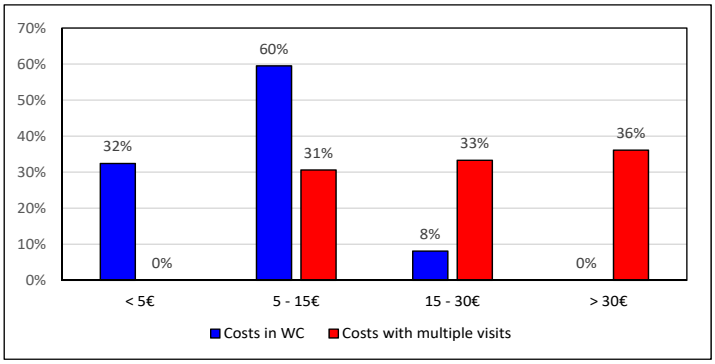


Along with satisfaction scores, the questionnaire attempted to identify other potential benefits of the WIC including time, money and information. In terms of time, approximately 92% of the parents believed they saved time with a single visit and the total of working parents mentioned missing work by 1 or less days. 13.5% of respondents were unemployed, retired or on sick leave.

In the same manner, 70.3% of the participants considered gaining more information about the procedure and ambulatory surgery in the WIC, 5.4% denied this benefit. A quarter of our population didn't respond to this question.

Finally, financial savings were explored in two different questions: money spent in one visit and eventual costs if the appointments required multiple visits to the hospital. These costs were categorized in 4 intervals: less than 5, 5 to 15, 15 to 30 and over 30 and presented in Figure 2. The intervals intended to include transportation, nourishments and other potential expenses and this was explained in the questionnaire for the participants. Regarding costs with a single visit to the hospital: 32.4% spent less than 5, 59.5% spent 5 to 15 and only 8.1% spent 15-30. The potential costs of the preoperative consultations being held in different days were: 29.7% 5 to 15, 32.4% 15 to 30 and 35.1% over 30.

Figure 2 Comparison between WIC's costs and multiple visits' estimated costs.



Discussion

Currently, ambulatory surgery is an exemplary model of quality and effectiveness [2] and continuous improvement is essential for its evolution and for better patient care.[5] Although multiple factors influence patients parents' satisfaction levels, their opinions are still a huge source of information and a valuable and essential tool to guide our changes and improvements in ambulatory surgery.[1] As evidence showed for the adult population, WIC is a pioneer model that improves efficiency while minimizing costs to the patient and the hospital, minimizing postponement of surgeries and absenteeism from work.[3]

With the focus in paediatric health care, the traditional models need to be enhanced.[4] WIC envisions to do this as it offers the convenience of a single visit to the hospital, lessening the time spent there, the days missing school and optimizing the process of preparing the children and their family for surgery.

Since 2012, WIC is widely used in our ambulatory surgery unit in the adult population. Despite the low volume of paediatric surgery in our hospital, the majority is being performed in ambulatory surgery. From July 2016, the WIC concept was progressively brought to this population and has outstanding results has showed by the questionnaire. Parents' satisfaction was the most important outcome evaluated that support the benefit for this change. Furthermore, financial savings and less time away from work, sustain this idea as well.

Notwithstanding these benefits, this study has numerous limitations including small sample size, questionnaire not validated and an absence of an organized and prospective trial. Further studies are needed in order to prove the theoretical benefits in the paediatric population.

Although our conclusions can't be extrapolated to other populations due to their limitations, WIC in our hospital is an excellent improvement in the paediatric preoperative setting of ambulatory surgery. It is easily applicable and will increase the quality and effectiveness and decrease the burden to the national healthcare system and parents.

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Ambulatory Dental Procedures in Children with Intellectual Disability: A Ten-Year Review

Morais I[1], Rodrigues JT[1], Peixoto C[1], Sousa I[1], Mesquita E[2], Morais A[1]

Abstract

Children with intellectual disabilities (ID) are often uncooperative for dental procedures so general anaesthesia is increasingly being used. Our goal was to assess anaesthetic management safety of children with ID proposed for dental procedures at our Ambulatory Unit. We conducted 10 year-long observational retrospective study of 138 children with ID (cases) and 138 without ID. Ages ranged from 4 to 17 years old, with male prevalence. The following were associated with cases: higher ASA and Mallampati scores, non-cooperation in airway assessment, inhalation anaesthesia and laryngeal mask utilization. No statistically significant differences regarding intra and postoperative complications. Children with ID were safely managed in ambulatory setting.

Keywords: Ambulatory Surgery, Children, Intellectual disabilities, Dental procedures, Safety.

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Introduction

Dental health problems are particularly prevalent among children with intellectual disabilities (ID) due to a myriad of factors such as poor oral hygiene or a cariogenic diet(1).

These children are often uncooperative for dental procedures due to their difficult behaviour management (1) and associated fear and anxiety (2), so in many cases they would hardly tolerate treatments under local anaesthesia.

Over the recent years, a growing number of patients require the presence of an anaesthesiologist to accomplish general anaesthesia (3), which has often been preferred in ID patients, anxiety issues, long and complex restorative and operative procedures, allergy or inefficacy of local anaesthetics, among others (2). It provides immediate pain relief and the opportunity to execute all the necessary interventions in the same operative time (3). The use of reversible, short and fast-acting anaesthetic agents, makes it possible to perform these treatments under GA in Ambulatory settings (4), whenever patients' characteristics favour and/or allow it.

There is scarce information on anaesthetic safety and postoperative complications and morbidity following GA in this particular population in Ambulatory Surgery in Portugal. The main goal of this study was to assess anaesthetic management safety of children with ID proposed for dental procedures at the Ambulatory Unit of a Portuguese central hospital compared with children without ID, over a ten year-long long period (January 2009-January 2019).

Methods

Our study was approved by the Ethic Committee of the Centro Hospitalar Vila Nova de Gaia/Espinho. We conducted an observational retrospective study that included 451 children that underwent dental procedures at our Hospital's Ambulatory Unit from January 2009 to January 2019.

From the total number of patients, we found 138 children with intellectual disabilities (International Classification of Diseases (ICD) 11th revision) that were unable to cooperate for the procedures and that were proposed for anaesthetic evaluation by the stomatology department. These were matched with 313 possible controls, based on a 1:1 approach, controlling for gender and age, and 138 children without ID were selected. The allocation of controls was randomized by blocks. Hence, for all male cases of each age block, a random sample of male controls of the same age was selected, reducing possible systematic errors. The same was performed for female cases. Whenever possible, the match was maintained at zero tolerance: no tolerance was allowed for gender and maximum tolerance allowed for age was +/- 1 year.

Groups were reviewed regrading: intellectual disability diagnosis, age, gender, systemic illnesses, American Society of Anaesthesiologists (ASA) Classification, Mallampati score, type of surgery, type of anaesthesia and intubation, anaesthetic drugs used, airway management difficulties, procedure duration and intra and postoperative complications. The information was collected by reviewing the patients' clinical charts regarding the mandatory preoperative anaesthetic consultation, perioperative records and postoperative stomatology consultations.

Statistical data analysis was conducted with SPSS (version 24; IBM Corporation, 2016). Variables were described with means (M) and standard deviations (SD) for quantitative variables, frequencies (n) and percentages (%). Variables association was measured with Chi-square test (X2) or Fisher exact test, when more than 20% of the crosstab cells had frequencies lower than 5. Results were evaluated at the $P < 0.05$ level of significance.

Results

Children' ages ranged from 4 to 17 years old. Demographics after case control matching showed no statistical differences ($p=0.606$) between cases ($M=10.01$; $SD=3.63$) and controls ($M=10.25$; $SD=3.82$) regarding age. Gender proportion was 61.6% males and 38.4% females for both cases and controls.

Table 1 shows separate diagnosis for all cases. The most frequent disability was pervasive development disorder/autistic disorder (43.5%), followed by Attention Deficit Hyperactivity Disorder (ADHD) (23.9%) and chromosomic abnormalities (19.6%).

The most common concurrent diagnosis was pervasive development disorder/autistic disorder with chromosomic abnormalities (12.3%).

Systemic diseases were dominant in cases (46.7%) comparing to controls (29.7%) ($p=0.004$).

As shown in Table 2, dental extraction was the most commonly performed surgery. Patients underwent dental extraction and dental

Table 1 Separate Diagnoses.

Description	n	%
Pervasive development disorder/Autistic disorder	60	43.5
ADHD	33	23.9
Chromosome abnormalities	27	19.6
Epilepsy	22	15.9
Cerebral Palsy	16	11.6
Changes in psychological development/ Educational skills	13	9.4
Mental Retardation	8	5.8
Malformation Syndromes	6	4.3

Table 2 Type of surgery.

	Controls	Cases	p-value
(χ2 test)			
Dental extraction	71 (51.4%)	87 (63.0%)	0.052
Dental extraction and restoration	48 (34.8%)	25 (18.1%)	0.002
Dental restoration	1 (0.7%)	20 (14.5%)	0.001
Mandible lesions extraction	8 (5.8%)	1 (0.7%)	0.036
Labial frenectomy	8 (5.8%)	4 (2.9%)	0.238
Mouth lesions excision	6 (4.3%)	1 (0.7%)	0.120
Complete sialoadenectomy	0 (0.0%)	1 (0.7%)	>0.990
Jugal mucosa biopsy	2 (1.4%)	1 (0.7%)	>0.990
Ulectomy	0 (0.0%)	1 (0.7%)	>0.990
Scaling/polishing	1 (0.7%)	1 (0.7%)	>0.990

restoration more often. We only present the results regarding the combination of dental extraction and restoration, but there were other less prevalent possible combinations of surgeries.

Higher Mallampati scores and non-cooperation in airway assessment were more associated with cases ($p<0.001$) (Table 3). We only found one reported case of predicted difficult airway, however there is a considerable lack of records.

Higher ASA scores were also more associated with cases as shown in Table 4.

All of the reviewed procedures were performed under GA and inhalation anaesthesia was more frequent in cases, as well as laryngeal mask utilization (Table 5). There was not great difference between the two groups regarding the choice of balanced anaesthesia or endotracheal tube use. Difficult airway was documented in 2.9% of the cases (vs 0.7%, $p=0.01$) with absence of records regarding this topic in 36.5% of the controls and 21.7% of the cases.

There was no significant difference between groups in terms of the various types of intravenous non-induction drugs used (Table 6).

Table 3 Airway assessment.

	Controls	Cases	p-value (χ2 test)
Mallampati Scores			
I	100 (72.5%)	68 (49.3%)	<0.001
II	25 (18.1%)	35 (25.4%)	
III	1 (0.7%)	4 (2.9%)	
Non-cooperative	0 (0.0%)	15 (10.9%)	
No records	12 (8.7%)	16 (11.6%)	
Predicted difficulty			
Yes	0 (0.0%)	1 (0.7%)	0.091
No records	13 (9.5%)	23 (16.7%)	

Table 4 ASA Scores.

ASA Scores	Controls	Cases	p-value (χ2 test)
I	95 (68.8%)	0 (0.0%)	<0.001
II	43 (31.2%)	113 (81.9%)	
III	0 (0.0%)	25 (18.1%)	

Table 5 Type of anaesthesia and airway management.

ASA Scores	Controls	Cases	p-value (χ2 test)
Inhalation	26 (18.8%)	43 (31.2%)	0.026
Balanced	68 (49.3%)	66 (47.8%)	
No records	44 (31.9%)	29 (21.0%)	
Airway Intervention			
Orotracheal tube	81 (58.7%)	80 (58.0%)	0.007
Laryngeal mask	7 (5.1%)	22 (15.9%)	
No records	50 (36.2%)	36 (26.1%)	

Table 6 Non-induction drugs.

	Controls	Cases	p-value (χ2 test)
Antiemetics/Anti-reflux	80 (58.0%)	85 (61.6%)	0.539
Anxiolytics / Analgesics / Anti-inflammatories	84 (60.9%)	91 (65.9%)	0.382
Antibiotics	58 (42.0%)	59 (42.8%)	0.903
Respiratory drugs	16 (11.6%)	20 (14.5%)	0.475
Cardiovascular drugs	21 (15.2%)	18 (13.0%)	0.604
Neuromuscular Blocking Reversals	28 (20.3%)	22 (15.9%)	0.348

Concerning induction agents, the combination of fentanyl, propofol and rocuronium was observed in 40.6% of the controls and 22.5% of the cases, whilst the combination of fentanyl and propofol was recorded in 20.2% of the controls versus 26.1% of the cases. Once again, the percentage of "no records" regarding induction drugs is fairly high (31.2% of the controls and 38.4% of the cases).

There was also no significant difference between groups when considering anaesthesia time (p=0.381) with a majority of surgeries lasting from 1 to 2 hours in both controls (45.7%) and cases (46.4%). Only 13 children without ID and 21 children with ID stayed in the operating room for more than two hours and 1 of the controls and 2 of the cases for more than three.

The same was true about intraoperative complications shown in Table 7: none verified in 70.3% of cases (vs 68.8%, p=0.109) with bradycardia as the most common complication in cases (5.8%).

Table 7 Type of anaesthesia and airway management.

	Controls	Cases	p-value (χ2 test)
None	95 (68.8%)	97 (70.3%)	
Bradycardia	1 (0.7%)	8 (5.8%)	
Bronchospasm	4 (2.9%)	4 (2.9%)	0.109
Hypotension	1 (0.7%)	1 (0.7%)	
No records	37 (26.8%)	28 (20.3%)	

There were no registers of middle term postoperative complications (investigated in the postoperative stomatology consultation) in both groups (p=0,035). In 21.9% of the controls and 12.3% of the cases there was no postoperative consultation nor there were no records available.

Discussion

As stated by the American Academy of Paediatric Dentistry (5), deep sedation or general anaesthesia may be extremely useful to perform dental treatments in specific patients with medical, psychological or behavioural conditions.

Normally, a visit to the dentistry/stomatology office is a cause of great anxiety to many children, so it is acceptable to assume that in ID children the scenario wouldn't be different (6). With GA, we facilitate treatment, achieving reduced levels of worry and apprehension and a more optimistic attitude towards this type of procedures in both patients and parents, ensuring a similar level of oral health care when compared to children without ID (5).

To succeed in this mission and assure the best care to these children in ambulatory settings, preparation and preanaesthetic evaluation are paramount (7). In our study, all children were evaluated by a trained anaesthesiologist, weeks prior to the procedure and an individualized anaesthetic plan was developed. In this consultation, patients' demographic features, systemic diseases, allergies, regular medication, ASA classification and airway features were assessed.

As previously reported, our population's age was between 4 and 17 years old. Similar to what has been reported in previous studies by Sitilci et al (2) and Norderyd et al (6), we also verified male prevalence (61.6%) in our research. Although we couldn't totally find an explanation for this result, Sitilci et al (2) point out the fact that male patients usually have superior physical strength and would have been harder to control with only behaviour management techniques, being more commonly proposed for GA.

Regarding systemic illnesses, although we don't specify accompanying diagnosis besides the main intellectual disability diagnose, we report higher ASA scores in ID children. This is congruent with Sitilci et al (2), defending that ID children have frequently other associated illnesses, that could lead to perioperative complications.

We also found higher Mallampati scores and higher rates of non-cooperation in airway assessment in our case group. Airway examination is a hard task in non-cooperating patients and in children with craniofacial abnormalities associated with various syndromes (2). Having said so, Mallampati score alone could be an insufficient tool to predict difficult airway management. The obtained higher Mallampati scores could have been, in some cases, due to insufficient collaboration and mouth opening.

The one predicted difficult airway detected in preanesthestic evaluation was managed in our ambulatory unit by anaesthesiologist choice with adequate preparation and there were no associated complications. The same care was taken when dealing with patients that didn't allow us to evaluate the airway.

When analysing the type of surgeries, both groups most commonly underwent dental extraction alone, followed by extraction and restoration in the same operative time and then solely dental restoration. On the contrary, Mallineni et al (3) reported higher percentage of restorative procedures in special need patients, as was also referred in other previous studies (8,9). Nevertheless, there are conflicting published results on this, with divergences in various paediatric age groups (3). We couldn't find an explanation and were surprised to notice that the combination of extraction and restoration in the same surgery was more prevalent in children without ID, since we believe it would be an advantage for ID children to perform both altogether. Regardless the order, these were the major surgical indications for general anaesthesia in children with and without ID.

The majority of our ID and non-ID children were managed with balanced anaesthesia in very equivalent frequencies. Whenever venepuncture was not successively achieved prior to induction, inhalation was the obvious choice. This is more frequent in children with ID, so we had 31.2% of them submitted to inhalation with sevoflurane (vs 18.8%). Although sevoflurane has been associated with agitation in small children (3), it continues to be the inhalation agent of choice for its tolerable smell, non irritation of the airway and safe profile regarding possible respiratory complications (2). Despite this, our anaesthesiologists favoured intravenous inductions whenever possible.

Invasive airway with an endotracheal tube was also the most common choice in both groups, mainly because of the surgical area and technique, but also related with systemic illnesses that would favour airway protection. Sitilci et al (2) and Mallineni et al (3) also mention nasal intubation as one of the most performed in dental procedures. Considering laryngeal masks, they were used most commonly in ID children. The choice of avoiding muscular relaxants is understandable in ID children in which airway assessment was particularly challenging or with cranial and facial abnormalities, escaping the risks of a "non-ventilate, non-intubate" situation. Having said so, we agree that a laryngeal mask is a good option whenever possible, if we believe there is a low risk of regurgitation and aspiration.

Difficult airway was documented in 2.9% of the cases (vs 0.7%, p=0.01). All of these cases were safely and timely managed without the need for rescheduling surgery or longer hospital stay. In 2008, Rodríguez et al (10) realized that airway management was progressively more complex in increasingly disabled patients. However, similarly to our and SitilciT. et al (2) results, statistically significant differences between groups were not found regarding difficult intubations.

There was also no significant difference between groups in terms of the various types of intravenous non-induction drugs used (antiemetics/anti-reflux, anxiolytics/analgesics/anti-inflammatories, antibiotics, respiratory, cardiovascular and neuromuscular blocking reversals). Although the use of preoperative sedatives in children is

a much debated issue (11), we only found a total of 8 children (4 of each group) requiring intravenous midazolam. Since one of our institution's protocols recommends oral midazolam (0.3-05mg/kg) for agitated children before entering the operation room, we believe there are records missing regarding this matter. This practice allows reduced levels of anxiety and better cooperation with inhalation (2), not only, but specially in children with ID.

It is established that ambulatory surgeries should have a limited time up to about 120 minutes (10), providing optimal use of operating rooms (3). Accordingly, we had a majority of surgeries lasting from 1 to 2 hours with no significant difference between groups, similar to previous revisions (3,10).

Regarding intraoperative complications, our findings were very encouraging as there were not statistically significant differences between groups. In a great majority of the situations, complications were absent. Bradycardia was the most common complication in cases (n=5), analogous with previously described results (2,10). In these cases, cardiac abnormalities were not found in the preanaesthetic visit, which is congruent with cases reported by Sitilci et al (2). It has been shown high incidence of bradycardia when sevoflurane is used for induction, but further studies would have to be performed with ID children, so it is only advisable to remember the possibility of this complication and avoid inhalation in Down Syndrome patients (2). Apart from this, we also had two cases of bronchospasm and hypotension in each group without statistically significant differences between them. On the contrary, Rodríguez et al (10) believe that the cases of bronchospasm of their study were related to the manipulation of more complex airways since they only found it in serious and very serious ID patients.

After the procedures, in post anaesthetic care units, various types of complications can occur: toothache (3), nausea and vomiting (3,12), respiratory depression, prolonged recovery, haemodynamic compromise (2), amongst others. In our study, we didn't find any records of any kind of complications. We trust this is due to three factors: first, there were no serious complications to report; second: we have very strict protocols regarding pain control and postoperative nausea and vomiting prophylaxis; and third: there was a lack of minor complications report. Knowing that we implemented the same protocols for both of the studied groups, we can conclude that we had a majority of uneventful immediate postoperative recoveries. However, further studies are needed in our institution to establish detailed postoperative incidents prevalence in children.

Postoperative stomatology consultation reviews did not unveil any middle term complications (1-3 months) in both groups.

It is of remarkable importance to say that in the majority of the studied variables there is an objectively high percentage of records absence. Although we have noticed an improvement in anaesthetic data registries in the last reviewed years, this is a significant limitation of our study. Future institutional policies will be implemented to improve this practice amongst our health care professionals team.

To conclude, children with ID were safely managed in our ambulatory setting. We provided successful dental health care treatments to a vast number of children, with previous planning and preparation. Equivalent standards of practice in this group of children compared to children without ID were assured.

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Comparison of Efficacy and Safety of Intrathecal Ropivacaine-Fentanyl and Bupivacaine-Fentanyl in Lower Abdominal and Lower Limb Surgeries

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Abstract

Aim: A prospective randomized clinical study was conducted to study the efficacy and safety of isobaric 0.5% ropivacaine-fentanyl with isobaric 0.5% bupivacaine-fentanyl intrathecally for lower abdominal and lower limb surgeries.

Methods: 100 patients aged between 18 to 65 years were randomized into two groups, n = 50 in each group. Group A received 3 ml of (0.5%) isobaric ropivacaine (15mg) with 25µg fentanyl and Group B 3 ml of (0.5%) isobaric bupivacaine (15 mg) with 25µg fentanyl. Spinal anesthesia procedure was standardized. Haemodynamic parameters, onset and duration of sensory and motor blockade, level achieved, regression and side effects were compared between the two groups.

Results: Onset of motor and sensory blockade was 15.6±3.4 min and 13.6±4.8min respectively in patients of group A as compared to 17.3±4.6min and 15.5±4.87min respectively in patients of Group B. The duration of sensory and motor blockade 132.08±16.3mins and 159.7±18.36min respectively in group A patients as compared to 175.7±15.7min and 205.9±29.8min respectively in patients of Group B ($p<0.05$).

Conclusion: Hence ropivacaine was safe and equally effective as bupivacaine in lower abdominal and lower limb surgeries with early motor recovery and providing early ambulation.

Keywords: isobaric bupivacaine, ropivacaine, spinal anesthesia; fentanyl.

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Introduction

Subarachnoid block is a commonly practiced anaesthetic technique in patients undergoing lower abdominal and lower limb surgeries [1]. It is a safe, inexpensive and easy to perform technique which also offers an advantage of post-surgical pain relief and avoid the various physiological and psychological phenomena which are vital for early mobilization and postoperative discharge [2] as pain can an unpleasant sensory and emotional, also considered as a vital signal of a life threatening problem [3]. Spinal anaesthesia has a quick onset and provides satisfactory sensory and motor blockade [4]. Administration of the appropriate choice and dose of local anaesthetic into the subarachnoid space results in rapid onset of deep surgical anaesthesia with a greater degree of success. The risks of general anaesthesia including complications due to airway management can be prevented like failed intubation, aspiration, venous thrombosis and pulmonary embolism [5].

Bupivacaine, levobupivacaine and ropivacaine have all been administered as intrathecal drugs [6]. Bupivacaine is the most commonly used local anaesthetic drug for subarachnoid block [7]. Bupivacaine has cardiotoxicity and central nervous system toxicity [8] apart from common complications like hypotension, bradycardia, urinary retention [9] which led to the identification of a better agents like ropivacaine.

Ropivacaine and bupivacaine are amino-amide local anaesthetics which structurally belong to the group of n-alkyl substituted pipecoloxylidide [10]. Ropivacaine has propyl group in comparison to butyl group of bupivacaine on the amine portion of pipecoloxylidide [11]. Apart from sharing various physicochemical properties with bupivacaine, onset time and duration of action of ropivacaine are also similar to the former but with less motor blockade when same volume and concentration are used [12]. This property is attributed to lower potency when compared to bupivacaine [13].

Ropivacaine is less lipophilic than bupivacaine and less likely to enter large myelinated motor fibres, which in turn produces relatively lower motor block and hence has a better motor sensory differentiation with hemodynamic stability [14].

The addition of adjuvants to ropivacaine has shown to improve the quality of intraoperative and postoperative pain relief without compromising its character such as early mobilization and voiding [15]. Fentanyl is the most common opioid which is used extensively as an adjuvant to local anaesthetics for enhancement of analgesia without increasing the depth of motor and sympathetic block [14, 15].

This study was conducted to study the efficacy and safety of isobaric 0.5% ropivacaine-fentanyl with isobaric 0.5% bupivacaine-fentanyl intrathecally for lower abdominal and lower limb surgeries.

Methods

After approval of the Institutional Ethical Committee, a prospective observational study was conducted on 100 patients undergoing major lower limb orthopaedic surgeries and lower abdominal surgeries. Written informed consent was obtained from all patients.

Inclusion criteria include patients of American Society of ASA physical status I or II of either sex, aged between 18 and 65 years, presenting for lower limb orthopaedic and lower abdominal surgery.

Exclusion criteria were patients having contraindications to spinal anaesthesia, a resting heart rate of <60/min, allergy to amide local anaesthetic, a significant history of substance abuse and pregnant women. Visual analogue score (VAS) for pain was explained to the patients pre-operatively as a 10 point scale wherein '0' indicates no pain '3' & above indicates severe pain warranting additional analgesics.

The study was conducted in 100 patients over a period of 18 months. They were divided into two groups of 50 patients each by using open

label road method of randomisation. Patients were randomly allocated to receive either intrathecal 3.5 ml of 15 mg of 0.5% ropivacaine with 25 µg fentanyl (Group A) or 15 mg of 0.5% bupivacaine with 25 µg of fentanyl (Group B).

Following arrival into the operation theatre, intravenous access was established, multipara monitor (electrocardiogram, non-invasive blood pressure and pulse oximeter) was attached and baseline parameters were recorded. After ensuring sterile conditions, spinal anaesthesia was performed, and the patient received one of the two study drugs. The drug combinations were prepared by the first anaesthesiologist, however various observations was made by the second anaesthesiologist.

Heart rate, blood pressure, respiratory rate and oxygen saturation was monitored throughout the study. A decrease of more than 25% from the baseline in the systolic blood pressure (SBP) was considered hypotension and decrease in the heart rate below 50 beats/min was considered bradycardia and treated with intravenous ephedrine/ mephentermine and atropine respectively.

The level of sensory and motor block was evaluated at 5, 10, 20, 30 min, 60min and at the end of surgery. The sensory block level was evaluated with the pin prick test [16], and the motor block level was determined according to the Bromage Scale [17] (0-no motor block, 1-inability to raise extended leg, able to bend knee, 2-inability to bend the knee, can flex ankle; and 3- no movement). During the tracking of the sensory block in patients, maximum sensory block level, time to achieve maximum sensory block, and its regression to L1 dermatome will be recorded. While tracking the motor block, time to achieve maximum motor block and the duration were recorded.

In the post-operative period, the time to first analgesic demand was noted when VAS will be or more than 3 and rescue analgesia was administered. Patients were observed for any discomfort, nausea, vomiting, shivering, pruritus, bradycardia and any other side effects and the need for additional medications was recorded.

The sample size was calculated using the formula –

$$n = \frac{2(Z\alpha+Z\beta)^2 x\ \sigma^2}{d^2}$$

With 95% confidence level & 85 % power, the sample size is 50 in each group.

Z alpha = 1.96 at 95% confidence level

Z beta = 1 at 85% power

σ & d are the combined standard deviation and mean difference respectively.

Data analysis was done using the ANOVA F test and Fischer's exact test.

*p value of <0.05 was considered significant.

Results

The mean onset time of sensory blockade (maximum sensory level in mins) was 13.64±4.82mins in group A as compared to 15.5±4.87mins in group B with significant statistical difference ($p<0.05$), whereas mean onset time of motor blockade was comparable between the two groups with 15.6±3.44mins in group A and 17.30±4.65mins in group B and the statistical analysis showed no significant difference as shown in Table 1.

The mean duration of sensory blockade (full sensory blockade recovery at T10) in group A was 132.08 ± 16.39min as compared to 175.70 ±15.9min in group B. The mean duration of motor recovery (bromage score back to zero) in group A was 159.70±18.36min and in group B was 205.9±29.87min, both of which had significant statistical difference ($p<0.05$), suggesting shorter duration of sensory and motor blockade in group A as shown in Table 2.

Table 1 Comparison of mean onset time of sensory and motor block between Group A and Group B in minutes.

Onset time	Group A	Group B	p	F
Sensory	13.64±4.82	15.5±4.87	0.04	1.92
Motor	15.6±3.44	17.30±4.65	0.058	2.08

Table 2 Comparison of mean duration of sensory and motor blockade between Group A and Group B in minutes.

Duration of Blockade (mins)	Group A	Group B	p value
Sensory	132.08±16.39	175.7±15.9	<0.05
Motor	159.70±18.36	205.9±29.87	<0.05

A level of T4 was achieved in 9 patients in Group A and 13 patients in Group B. T6 level was achieved in 28 patients in group A and 33 patients in Group B, whereas T8 level was achieved as a maximum sensory level in 12 patients in Group A and 4 patients in Group B. Most of the patients in Group A (56%) had a maximum sensory level of T6, which was comparable with Group B where the maximum number of patients (66%) achieved a level of T6, however there was no statistically significant difference between the two groups($p<0.081$) as shown in Table 3.

Table 3 Maximal sensory level (MSL) achieved in Group A and Group B between dermatomal level T4, T6, T8 and T10. (n and %).

MSL	Group A	Group B	Total
T4	9 (18%)	13 (26%)	22 (22%)
T6	28 (56%)	33 (66%)	61 (61%)
T8	12 (24%)	4 (8%)	16 (16%)
T10	1 (2%)	0 (0%)	1 (1%)
TOTAL	50 (100%)	50 (100%)	100 (100%)

We found no statistically significant difference between the groups in achieving the Bromage score of 1, whereas time taken to achieve the Bromage score of 2 & 3 was shorter in group A than in B with statistically significant difference ($P<0.05$) as shown in Table 4.

The comparison of quality of analgesia between the two groups depicts that 13.88% of the patients in group A and B had excellent pain relief (score 1). In both group A and B 8% of the patients had good pain relief. In group A, 2% patients had fair pain requiring additional analgesics as compared to 4%patients in group B. 2% patients in group A had severe pain requiring general anaesthesia as shown in Table 5.

The comparison of mean systolic blood pressure values between the two groups signifies that the differences are significant from 30min interval onwards (<0.05) with steadier blood pressure in group B as shown in Table 6.

Diastolic blood pressures were comparable between the groups with no statistically significant difference as shown in Table 7.

Table 4 Comparison of mean time duration to achieve individual Bromage score between Group A and Group B in minutes.

		N	Mean	Std deviation	95% Confidence Interval for mean		t value	P
					Lower bound	Upper bound		
BROM 1	Group A	50	6.90	2.452	6.20	7.60	1.448	0.151
	Group B	50	6.20	2.382	5.52	6.88		
BROM 2	Group A	50	10.30	3.436	9.32	11.28	2.312	0.023
	Group B	50	11.90	3.483	10.91	12.89		
BROM 3	Group A	50	14.90	3.710	13.85	15.95	2.540	0.013
	Group B	50	17.00	4.518	15.72	18.28		

Table 5 Comparison of analgesic score between Group A and Group B in terms of visual analogue scale score. (n, %).

Analgesic Score	**Group**		**Total**
	A	B	
Excellent	44 (88.0%)	44 (88.0%)	88 (88.0%)
Good	4 (8.0%)	4 (8.0%)	8 (8.0%)
Fair	1 (2.0%)	2 (4.0%)	3 (3.0%)
Severe Pain	1 (2.0%)	0 (0.0%)	1 (1.0%)
Total	50 (50.0%)	50 (50.0%)	100 (100.0%)

Table 6 Systolic blood pressure between Group A and Group B at baseline, 5 minutes, 10 minutes, 20 minutes, 30 minutes and at one hour after start of surgery in mm Hg. (Mean + SD).

	Group A	**Group B**	**t Value**	**p**
Baseline	123.2 +11.9	124.8 +9.5	0.75	0.454
5 min	111.9 +14.8	114.7 +15.5	0.90	0.368
10 min	113.1 +11.3	117.6 +11.7	1.94	0.055
20 min	115.6 +10.6	118.8 +11.4	1.43	0.156
30 min	116.0 +9.9	120.7 +10.5	2.27	0.025
AT END	119.5 +9.7	125.4 +8.4	3.26	0.002
1 hr	120.6 +9.3	126.9 +8.5	3.58	0.001

Table 7 Diastolic blood pressure variation between Group A and Group B at baseline, 5 minutes, 10 minutes, 20 minutes, 30 minutes and at one hour after commencement of surgery in mm Hg. (Mean + SD).

	Group A	**Group B**	**t Value**	**p**
Baseline	73.74 + 7.5	74.0 + 6.3	0.22	0.830
5 min	68.2 + 7.9	67.7 + 7.4	0.33	0.746
10 min	68.9 + 5.9	69.8 + 5.1	0.80	0.426
20 min	70.3 + 5.7	70.0 + 4.9	0.28	0.779
30 min	70.3 + 6.1	69.6 + 10.4	0.37	0.709
AT END	71.5 + 5.1	71.4 + 4.5	0.10	0.917
1 hr	71.5 + 6.7	72.3 + 4.2	0.65	0.519

Discussion

Over the past many decades, subarachnoid block has been well established in modern day practice as a safe and effective anaesthetic technique [18]. There has been an upsurge of interest in recent times in newer agents that can be employed for subarachnoid block that may offer quicker recovery and early ambulation with fewer side effects.

The demographic features, mean duration of surgery and the ASA physical status were comparable between the groups. Baseline hemodynamic parameters were also comparable between the groups. The maximum sensory level achieved and the sensory block regression was tested in both the groups by using pin prick sensation.

A maximum sensory level of T6 was achieved in 56% of patients in the group A compared to 66% in group B, maximum level of T4 was achieved in 18% patients of group A compared to 26% in patients of group B. A maximum sensory level of only upto T8 was achieved in 24% of patients in group A as compared to 8% in group B. The upper level of sensory blockade was higher in patients of group B than compared to group A.

Malinovsky et al [19] compared intrathecal isobaric ropivacaine 15mg versus bupivacaine 15mg in patients who underwent TURP and found that cephalad spread of sensory block was higher with bupivacaine compared to ropivacaine, similar to our findings.

The mean onset of sensory blockade in our study in group A was 13.64±4.82min and 15.5 ±4.87min in the group B, which is statistically not significant. Similar findings were observed by Kallio et al[20] where they compared plain solutions of ropivacaine and bupivacaine 15mg each and found that time of onset of sensory block was comparable. Two segment regression time was significantly shorter with group A 65.30±10.89min compared to 80.80 ± 8.9min with group B; regression time to T10 segment was also shorter with group A [85±14.17min] compared to group B[111.04±10.4min]. Clearly, recovery from sensory block was more rapid with ropivacaine group compared to bupivacaine group.

The degree of motor blockade was assessed by using the modified Bromage score where a score of 3 indicates onset of motor blockade. The onset of motor blockade was rapid in both the groups with mean onset of 15.6 ± 3.4min in group A and 17.3 ± 4.6min in group B; these observations were comparable to previous studies by the McNamee et al [21] and Kallio et al [20]. The time required to achieve (individual Bromage score) was also similar in both groups with no statistically significant difference which is supported by a study conducted by Gudul Z et al [14] by comparing isobaric solutions of ropivacaine 7.5mg/ml and bupivacaine 5mg/ml.

In our study the duration of sensory blockade was assessed at the level of T10 and it is seen that the mean duration of sensory blockade

in group A was significantly shorter when compared with group B. Similar findings were noted by Mantouv et al [22] who studied plain ropivacaine versus plain bupivacaine for lower abdominal surgery.

Gudul et al [14] et al compared isobaric ropivacaine 15mg and isobaric bupivacaine 15mg in patients undergoing elective surgeries and concluded that duration of motor blockade with ropivacaine is shorter than bupivacaine which provides a better post-operative recovery. This study supports our findings where the mean duration of motor blockade in group A was 159.7±18.3min and in group B 205.9±29.8min indicating significantly lower duration of motor blockade in ropivacaine group.

Both the groups provided excellent analgesia with only one patient having mild discomfort, not requiring additional analgesics and another patient required additional analgesics due to inadequate pain relief in ropivacaine group.

We did not note any significant differences between the two groups regarding haemodynamic variables, heart rate and oxygen saturation. However, the fall in systolic and the diastolic blood pressure from the 5min interval was noticed more in the ropivacaine group, which was statistically not significant.

In group A, hypotension was noticed in 3 patients and in 3 other patients, hypotension was associated with bradycardia. In group B, 1 patient had an episode of hypotension and 3 other had hypotension and bradycardia. The above events were not statistically significant, thus concluding no significant hemodynamic instability in both the groups.

Hence based on our study, we conclude that use of ropivacaine for intrathecal anesthesia in the lower abdominal and lower limb surgeries provided an adequate level of block for the surgery with faster onset of sensory and motor blockade, lesser duration of motor blockade with good analgesia and stable hemodynamics.

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Short-Term Morbidity Associated with Ambulatory Sentinel Lymph Node Biopsy: A Spanish Tertiary Care Hospital Based Study and Literature Review

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Abstract

Aim: To determine the surgical morbidity of SLNB performed as a major surgery procedure in an ambulatory outpatient setting.

Methods: Observational, retrospective study of 303 consecutive patients undergoing SLNB for melanoma. Overall complication rate was 22.1% (67/303). Risk factors were the location of the primary tumor on limbs (49.2%) and groin SLNB (52.2%) At the last follow-up (median: 46 months), all complications had been resolved. No cases of lymphedema, systemic complications or mortality were detected.

Conclusions: Safety of ambulatory SLNB was demonstrated. The complication rate is slightly higher than reported, due to the overestimation of seroma incidence

Keywords: Sentinel lymph node biopsy, melanoma, ambulatory surgical procedures, morbidity.

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Introduction

Sentinel lymph node biopsy (SLNB) is a well-established method of staging the regional lymph nodes for patients with melanoma. The American Society of Clinical Oncology (ASCO) and the Society of Surgical Oncology released joint clinical practice guidelines in 2018 on the use of SLNB for patients with melanoma [1].

Although it is often stated that SLNB is a minimally invasive procedure associated with few complications, a lack of data exists to determine the morbidity associated with this procedure accurately. As other authors highlighted [2], the quality of melanoma surgery needs to be evaluated based on oncological outcomes and complication rate. There is no published agreement on complication rates for SLNB. Consequently, there are no agreed standards by which surgeons can audit their practices.

The purpose of this study was to determine the surgical morbidity of SLNB performed as major dermatological surgery procedure in an ambulatory outpatient setting, and to identify population demographics, histopathological features of melanoma and other preoperative or perioperative risk factors for complications following this technique.

Material and Methods

Patients and study design

This was an observational study of all patients who underwent SLNB for invasive cutaneous melanoma in the Ambulatory Mayor Surgery (AMS) unit of our tertiary hospital, during the period from 2008 to 2017. Retrospective review of medical records from procedures performed at Dermatology Department and other Departments (Oral and Maxillofacial Surgery, Plastic and Reconstructive Surgery and General Surgery/Breast Unit) were gathered.

Ethics and policy

Informed consent was obtained before surgery in all cases. The confidentiality of the information was guaranteed according to the effective Spanish legislation. The study was approved at the Institutional Review Boards of our center.

Treatment approach and follow-up

Patients of any age with pathologically proven cutaneous melanomas T 1b and clinically negative regional lymph nodes, were offered wide local excision with appropiate margins for tumor thickness and SLNB for surgical staging.

All patients underwent preoperative lymphoscintigraphy using 1-2 mCi of 99mTc sulfur colloid injected intradermally around the melanoma or biopsy site the morning of or the afternoon before the SLNB, to identify all draining nodal basins. A hand-held gamma probe was used during surgery to guide sentinel lymph node (SLN) detection. The protocol specified that all palpable adenopathies and all nodes 10% of the most radioactive, or hottest node should be removed and designated SLNs.

The patient was offered a complete lymph node dissection (CLND) if the result was positive with oncological appraisal at the time of admission for this procedure. The patient with a negative result had regular clinic follow-up. Retrospective evaluation of complications was performed by using detailed case report forms related to SLNB. Reports included details such as the site and severity of the complication and the extent of treatment, including the need for hospital admission or reoperation.

If a disease manifested in this group at a later date, then the patient was restaged and offered therapeutic lymph node dissection (TLND) if positive nodal involvement was confirmed.

Histopathology assessment

All SLNs underwent histological analysis with hematoxylin and

eosin staining at multiple levels, followed by immunohistochemical staining for S-100 protein. SLNs were divided into blocks on the basis of lymph node size; at least three sections per block were evaluated by hematoxylin and eosin staining, and two sections per block were stained for S-100 protein and Melanoma Triple Cocktail (HMB45; melan-A, tyrosinase) antibodies. Intraoperative frozen-section analysis of SLNs was not performed; therefore, patients undergoing CLND for positive SLNs returned to the operating room for a separate procedure at a later date.

Definitions

Regional lymph node basins were defined as parotid an neck, axilla, inguinal, and "others" (popliteal, elbow).

We broadly defined complications as any adverse event documented by any provider during postoperative follow up visits[3]. Complications specifically identified on the follow-up data forms included hematoma/seroma formation, lymphedema, wound separation, wound infection or "other" complications.

As uniform criteria for all these complications are not available, we considered:

- *Seroma* as any palpable fluid collection, although it is debatable whether the criteria for seroma should be a certain diameter, since many small seromas will resolve without active treatment. As other authors[4], we consider that seroma should be defined as a condition requiring intervention, because as long as it does not impose a problem for the patient, it is questionable whether it should be regarded as a complication or just a natural part of the healing process.
- *Lymphedema* as any swelling of the involved limb/s and classified according to clinical severity. Mild (grade I) lymphedema was minor swelling with or without pitting, which reduced upon limb elevation. There was neither functional impact nor treatment necessary. Moderate (grade II) lymphedema was defined by the presence of pitting, which seldom reduced with limb elevation or required intermittent treatment. Severe (grade III) lymphedema was significant, irreversible limb swelling requiring continuous treatment, such as a compression garment [5]. Limb measurements were not performed.
- *Surgical site infection* (SSI) as any wound erythema prompting antibiotic treatment, being culture positive or clinically evident[4].

Data collection and statistical analysis

Patient demographics, clinicopathological characteristics of the primary melanoma and regional lymph nodes, complications and follow-up were gathered for analysis.

Statistical Package for the Social Sciences (SPSS, version 24.0) was used for the data analysis. Statistical comparison of continuous variables means was performed using the Mann–Whitney U or T-student test, while comparison of categorical variables was made by Ji- squared ($\chi 2$) analysis or Fisher's exact test, where appropriate. P values 0.05 were considered significant.

Limitations of the study

Information bias: Because of the retrospective design of the study, some important clinical characteristics (i.e., comorbidities) were not recorded.

Results

The database was created in 2008 and include 303 patients, 196 of which underwent SLNB in our Department and 107 patients in other departments.

The SLNB were all conducted on Caucasians; the sample group consisted of 182 women (60.1%) and 121 men (39.9%), aged from 1 to 93 years (mean of 61.2 years, median of 64.0 years). The primary tumor location was: 101 (33.3%) in the trunk, 119 (39.3%) in limbs, 38 (12.5) in hands and feet and 44 (14.5%) in the head and neck region. The mean thickness of the primary tumor was 2.66 mm. Two-hundred and thirty-nine (78.9%) had a negative SLNB whilst 52 (17.2%) had a positive result. Regarding the number of SLN excised, only one node was harvested in 113 cases (37.3%), two nodes in 102 (33.7%) and three or more nodes in the remaining 88 (29.0%). A single draining basin was identified in 301 patients (99.3%).

The overall complication rate was 22.1% with 67 complications. The most common complications was seroma formation (n=45; 14.9%), followed by wound infection (n=8, 2.6%), hematoma (n=6; 2.0%), perioperative hemorrhage (4 cases, 1.3%), nerve injury (n=2; 0.7%), wound separation (n=1, 0.3%) and Mondor disease (n=1, 0.3%) No cases of lymphedema were detected. By the last follow-up, all complications had been resolved. The median follow-up duration was 46 months.

Complications resulting in hospital readmission occurred in 8 cases (2.6%), 6 for serious wound infections that required intravenous antibiotics and 2 for perioperative hemorrhage. Systemic complications, perioperative and postoperative procedure-related mortality was zero. The univariate analysis, comparing patients with and without complications, only showed differences when the location of primary melanoma and lymph node basin were analyzed (p=0.03): The highest complication rate of 52.2% (35/67) was observed in patients undergoing SLNB of the groin for primary melanoma of the lower extremity. Primary melanoma of the lower extremity was also significantly related to a higher rate of wound complications (49.2%, 33/67). The strong statistical correlation between this location and drainage to the groin suggests the biopsy site in the groin, rather than the location of the melanoma on an extremity, is responsible for the wound morbidity.

Discussion

SLNB vs Elective lymph node dissection (ELND)

Lymphatic mapping with SLNB is the standard approach for the management of patients with melanoma in whom there is a significant risk of regional node metastasis. It is a less invasive alternative to ELND for pathologic nodal staging, provides important prognostic information and permits the identification of patients with a positive SLN who may be candidates for adjuvant therapy.

Recent meta-analysis[4] of 416 records of inguinal lymphadenectomy showed following complications rates: overall complications, 52% (44-60%); lymphorrhea, 29% (0-71%); seroma, 23% (18-29%); infection, 21% (15-27%); wound breakdown, 14% (8-21%); skin edge necrosis, 10% (6-15%); hematoma, 3% (1-5%); and lymphedema, 33% (25-42%).

Although most centers have accepted the premise that SLNB is associated with low surgical morbidity when compared with ELND, limited evidence is available to support this assertion. The only study that directly examines the complications of SLNB with those of ELND is Schrenk et al[6]. The study compared the morbidity rate of two groups of 35 women with breast cancer. The first group underwent

SLNB whereas the second group had level I and II axillary dissection. Formal axillary node dissection was associated with significantly increased arm circumference and higher rate of subjective arm lymphedema, numbness, pain, and motion restriction.

SLNB vs SLNB followed by CLND

In the case of melanoma, at least seven studies have shown reduced SLNB morbidity compared with SLNB followed by CLND (Table 1):

- The first report regarding the complications of SLNB from a large multicenter prospective study was the Sunbelt Melanoma Trial (SMT) which showed that SLNB is associated with fewer complications than regional lymphadenectomy[7]. At a median follow-up of 16 months, the overall complication rate was significantly lower when only SLNB was performed (5% vs 23% for SLNB plus completion lymphadenectomy). The lower rate of complications included wound infection, lymphedema, hematoma/seroma, and sensory nerve injury. As we discuss later, this incidence of complications reported by SMT for SLNB is lower than that those reported by several smaller single institution series[8]:
- Initial report about morbidity of SLNB published by Morton et al[9] with data from MSLT-1 showed that the low (10.1%) complication rate after SLNB increased to 37.2% with the addition of CLND; CLND also increased the severity of complications.
- In other prospective study[5], 1521 patients who underwent SLNB, CLND following a positive SLNB and TLND in the axilla and groin were included. The overall rate of early complications associated with SLNB was significantly higher in the groin compared with the axilla (14% versus 5%, P = 0.0001) and fewer than for lymphadenectomy. Early complications were similar for CLND and TLND in the groin (49% versus 43%, P = 0.879) and axilla (28% versus 33%, P = 0.607).
- - A retrospective study[10] of 493 SLNB and 147 SLNB followed by CLND also detected higher early and late incidence of complications for SLNB in the groin (24%) than the axilla (10%) and fewer than for CLND (84% and 60%, respectively).
- Another retrospective study of 416 patients[8], showed not only an overall rate of complications significantly higher than that observed for SLNB (19.5% vs 5.9%), but also a predominance of chronic vs auto-resolved lymphedema in those who also underwent CLND (5/6 vs ½).

Smaller series have found similar differences, but the relation with lymph node basin was not specifically studied:

- A retrospective study[11] of 203 patients found post-operative complications of SLNB (neuropathic pain, infection, seroma, hematoma, lymphedema) in 12% of patients (24/197) and in 14% of patients (6/ 42) who underwent additional CLND, including lymphedema[3], hematoma[1], neuropathic pain[1] and complex regional pain syndrome[1].
- Mixed prospective and retrospective study[12] of 241 patients showed that the complication rate was 6% after SLNB and 29% after CLND.
- A retrospective study[13] showed that persistent sequelae were less frequent after SLNB (7.5%) than after SLNB plus CLND (30%), being lymphedema the most common in both groups.

One caveat regarding these analyses should be mentioned: the comparison was not between SLNB and ELND, but between SLNB alone and SLNB followed by CLND. Although it is possible that CLND after SLNB, which involves two operative procedures, is more morbid than ELND alone, the rate of complications in the SLNB plus CLND group in these studies was similar to that reported for ELND in other studies[7].

CLND vs TLND

Two different types of lymph node dissection could be considered in melanoma patients with demonstrated lymph node metastasis:

- CLND: lymphadenectomy of all remaining lymph nodes in the affected basin following a positive SLNB in the absence of clinically palpable disease[13].
- TLND: lymphadenectomy presented as an option for those who have clinically palpable lymph node involvement, either following SLNB or in the absence of SLNB[14].

A paucity of literature exists comparing the morbidity of CLND and TLND[15]. In 2010, published data from MSLT-1 [16] showed no significant difference in acute morbidity, but lymphedema was significantly higher in the TLND group (20.4% vs. 12.4%, p=0.04). Length of inpatient hospitalization was also longer for TLND.

A recent systematic review of complications following CLND versus TLND for melanoma was published[17] and 18 articles were included. Comparing the group of 1627 patients who underwent TLND (1627 patients) vs the group of CLND (1929 patients), the overall incidence of surgical complications was 39.3% (95% CI 32.6-46.2) vs 37.2% (95% CI 27.6-47.4). were as follows: wound infection 25.4% (95% CI: 20.9-30.3) vs 21.6% (95% CI: 13.8-30.6); lymphedema 20.9% (95% CI: 13.8-29.1) vs 18% (95% CI: 12.5-24.2) and seroma 20.4% (95% CI: 15.9-25.2) vs 17.9% (95% CI: 10.3-27). The complication rate was sightly lower for CLND, but without any statistical significance.

There are few prospective studies examining lymphoedema incidence when radiotherapy is added to TLND [18], but some of them showed that rate was increased[5].

Overall complications of SLNB

Although SLNB is not without morbidity, most of the complications associated are minor. In their original description of the procedure, Morton et al[19] quote an incidence of 5.5% seroma and 4.8% infection for all lymph node basins. We reviewed a meta-analysis[20] with 9047 patients from 21 individual studies published between 2000-2015. The overall incidence of complications was 11.3% with a highly variable range reported (from 1.8 to 30). These variations likely stem from a considerable heterogeneity in available studies. Difficulties for analyzing data reported are mainly due to[20]:

- Design of the studies: Many of the studies presenting morbidity data are small in scale, retrospective in design, with a lack of high quality evidence available.
- Poor reporting information: complications presented as a secondary measure, with imprecise definitions and grouped complications (presenting data as "wound complications") means that the data is not standardise and results are impractical to establish conclusive comparitions.
- Length of follow up periods across the studies is heterogeneously presented as the mean, median or range. Some studies omit the length of follow up, or it is not transparently presented.

In 2015, the Cochrane Collaboration published a systematic review[21] with the primary outcome measure being overall survival after lymph node dissection for melanoma in 2001 patients. A subgroup analysis of risk ratios was performed comparing surgical morbidity (within 30 days) in the dissected lymph node basin between patients treated with wide excision and SLNB versus wide excision and observation, which unsurprisingly showed zero complications in

Table 1 Complication rates for SLNB compared with SLNB followed by CLND.

Reference	Design	n	Age of patients included	Type of complications	SLNB (%)	SLNB + CLND (%)
Theodore et al [5]	Prospective, single centre	SLNB: 847 SLNB+ CLND: 100	12-85	TOTAL Seroma Surgical-site-infection	8 4 2	40 26 22
Wrightson et al [7]	Prospective randomised	SLNB: 1676 SLNB + CLND: 444	18-70	TOTAL Wound separation Wound infection Severe infection Haemorrhage Lymphoedema Haematoma/seroma Skin graft requirement Thrombophlebitis Deep venous thrombosis Pneumonia Urinary tract infection Cardiac complication Pulmonary complication Sensory nerve injury Motor nerve injury Other	4.6 0.24 1.08 0 0.09 0.66 2.31 0 0.09 0.09 0 0 0 0.14 0.14 0.09 0.42	23.2 1.58 6.98 1.35 0.45 11.7 5.9 0 0 0.23 0 0.23 0 0 1.8 0.45 4.1
Roaten et al [8]	Retrospective, single centre	SLNB: 339 SLNB + CLND: 77	NA	TOTAL Seroma Nerve injury Wound infection Lymphoedema Haematoma Dehiscence Postoperative pain Suture granuloma Myocardial infarction Thoracic duct injury Lymphocoele	5.9 1.2 0.9 0.9 0.6 0.6 0.6 0.6 0.3 0.3 NA NA	9.5 NA 1.3 6.5 7.8 NA 1.3 NA NA NA 1.3 1.3
Morton et al [9]	Phase III RCT	SLNB: 937 SLNB + CLND: 234	18-75	TOTAL Wound separation Seroma/haematoma Infection	10.1 1.2 5.5 4.6	37.2 3.0 23.1 15.8
Jørgensen et al [10]	Retrospective, single centre	SLNB: 493 SLNB+ CLND: 147	NA	TOTAL Lymphoedema Seroma Reoperation Surgical-site-infection	22.3 4.1 9.3 0.4 8.5	72.8* 34 57.1 16.3 46.2
Chakera et al [12]	Mixed prospective and retrospective	SLNB: 241 SLNB + CLND: 49	18-85	TOTAL Infection Seroma Lymphoedema Haematoma	6* 2.1 4.7 0.8 0.8	29* 14.3 16.3 14
Van den Broeck[45]	Mixed prospective and retrospective	SLNB: 241 SLNB + CLND: 49	17-85	TOTAL Infection Seroma Haematoma Lymphoedema Bleeding Neuralgia	11 1.6 7.2 1 1.3 - 1	78 38 58 - 11 4.4 -
Espinosa-Pereiro [13]	Retrospective	SLNB: 94 SLNB + CLND: 30	Average: 56	TOTAL Impaired scarring Infection Seroma Lymphoedema Wound separation	30.9 10.6 9.6 5.3 4.3 4.3	60.0 13.3 13.3 20.0 26.7 0

the unoperated observation group versus 106 complications in 937 patients of the SLNB group (11.3%). This result is equal to the pooled proportion of complications in the meta-analysis[20], although in a much smaller sample size.

Comparing our series with both reviews, we detected a higher overall rate of complications of 22.1%, which is most probably due to the inclusion of very small seromas (Table 2).

Specifical complications of SLNB

Meta-analysis[20] calculated that the incidence of seroma was 5.1% (95% CI: 2.5-8.6); infection was 2.9% (95% CI: 1.5-4.6); lymphoedema was 1.3% (95% CI: 0.5-2.6); haematoma was 0.5% (95% CI: 0.3-0.9) and nerve injury was 0.3% (95% CI: 0.1-0.6).

Hematoma and seroma formation are the most frequent complication, which usually is of no long-term consequence. Ligatures or metal clips to control lymphatic dissection field may help to minimize the incidence of haematomas and seromas, although some authors related their use to higher risk of sensitive nerve entrapment and temporary postoperative pain[22]. A meta-analysis[20] showed that the most common reported complication was seroma in 16 articles (n = 386 of 6750 patients, 5.72%), with a crude rate ranged from 0% to 38%. Our data revealed a 14.9% incidence of seroma after SLNB, but comparison cannot be established as we considered any palpable fluid collection. In contrast, only 2% developed haematoma.

We only had one case with persistent seroma after six months in a patient with congestive heart failure. Some authors[23] found persistent seromas at the SLNB site (7%) in patients who did not had CLND. Concomitant medical illness that can cause persistent seromas such as congestive cardiac failure, renal failure or low blood protein were not reflected.

SSI: We detected a rate of wound infection after SLNB of 2.6%, consistent with meta-analysis reported (1%), which showed that it was the second most common reported complication in 16 articles (n = 242 of 7687 patients), with a crude rate ranged from 0.3% to 19%[17]. It is comparable to that of a clean operative procedure and is significantly less than that of the CLND (6%[24] to 29%[25]).

As previously commented, the number of seroma aspirations increased the risk of SSI and lymphoedema[10]. We could not evaluate the influence of this variable, as it was not recorded in most cases.

Similar to other studies[7], the most frequent complication resulting in hospital readmission in our series was serious wound infections that required intravenous antibiotics.

Lymphoedema after axillary or inguinal lymphadenectomy is not infrequent and is perhaps the most dreadful complication associated with nodal staging procedures. Meta-analysis showed that it was the third most commonly reported complication of SLNB, included in 18 reports (n = 135 of 7770 patients, 1.3%), with a crude rate ranged from 0% to 17%. In our series, no cases of lymphoedema after SLNB were detected.

Although lymphoedema was attributed to the externt of lymphatic disruption and the number of lymph nodes excised during the SLNB or CLND procedure, wide local excision of extremity melanomas could contribute to this incidence of lymphedema[22]. Also, lymphoedema was not evaluated (in our and most studies) by prospective measure of limb volume or circumference, but was defined as clinically apparent swelling of the extremity on the basis of history and physical examination, so some cases of minor limb swelling could have been missed[7].

SMT[7] found a 0.7% risk of lymphoedema among patients undergoing axillary or inguinal SLNB (14 of 2083 patients), while the rates of lymphedema after axillary and inguinal CLND were 4.6% and 31.5%, respectively. Ten (71%) of these 14 patients had lymphedema of the lower extremity after inguinal SLNB. Lymphoedema was also significantly more common for patients undergoing inguinal CLND compared with axillary CLND (31.5% vs 4.6%; $P < 0.0001$).

A previously mentioned retrospective study[10] comparing 493 SLNB vs 147 SLNB followed by CLND cases also showed that the incidence of lymphoedema after CLND (34%) was substantially higher than after SLNB (2%), and is related to the extent of lymphatic disruption, the number of lymph nodes removed, the number of metastatic lymph nodes, SSI, reoperation and number of seroma aspirations. SSI was the most significant independent risk factor for developing lymphoedema. Additionally, patients that developed postoperative seroma were at an increased risk of also developing SSI. The risk of lymphoedema was significantly larger following inguinal incisions compared to axillary incisions for both SLNB and CLND. Although obesity and increasing age has previously been associated with a risk of lymphoedema[25], these parameters were not found to be independent risk factors.

Other local complications (reported but not fully enumerated) included nerve injury (motor or sensory dysfunction), wound dehiscence, post-operative pain, keloid scar, suture granuloma, skin graft requirement, lymphatic fistula and persistent skin staining of blue dye[20].

Out of this group of post-operative complications, we only detected wound dehiscence in 0.2% of patients. Our study also included patients with melanoma in the head and neck region undergoing SLNB involving the parotid basin. Albeit some surgeons have proposed that SLNB may limit complications associated with parotid dissection—specifically, facial nerve injury—others have disproved this argument because the facial nerve is not exposed properly,

Table 2 Complications of SLNB in patients with melanoma.

Type of complication	Cochrane Collaboration [21] N=937)	Meta-analysis[20] (95% CI) (N=9047)	Our series (N=303)
Infection	4.59%	2.9% (1.5-4.6)	2.6%
Seroma	5.54%	5.1% (2.5-8.6)	14.9%
Haematoma		0.5% (0.3-0.9)	2.0%
Lymphoedema	0.6%	1.3% (0.5-2.6%)	0.0%
Nerve injury	-	0.3% (0.1-0.6)	0.7%
Wound separation	1.2%	-	0.3%
TOTAL	11.3%	11.3% (8.1-15.0)	22.1%

and, therefore, unintentional damage could occur because of the limited dissection field. The morbidity associated with SLNB of the parotid has been reported to be 2.6% [26] to 4%[27]. Some authors have identified facial nerve dysfunction in 10% patients, but in all of them returned to preoperative status[28]. In this study, we also found minor, transient facial nerve paresis in 1.2% of patients as complication associated with parotid SLNB. However, we did not see any cases of seroma, infection, definitive section, or paresis.

We not detected other sensory complications in our series. Wasserberg et al[29] observed a significant relation between nerve-related complications and age younger than 50 years, axillary site, and number of excised sentinel nodes (p=0.003, 0.04 and 0.02, respectively).

AWS (Axillary web syndrome) or Mondor disease of the axilla is a complication frequently described in the breast cancer literature. It is characterized by a palpable cord that arises in the axilla that may extend distally to involve the medial arm, antecubital fossa, and forearm and is associated with pain and restriction of movement across the involved joint space. AWS has been reported as having an incidence as high as 20% after SLNB and 72% after CLND for breast cancer and usually presents within 12 weeks of the operation. AWS has also been reported after trauma, infection, excessive physical activity, and inflammatory conditions. The incidence of AWS in the unique retrospective study[30] with patients undergoing SLNB for clinically node-negative melanoma of the upper extremity and trunk, was equal or higher than "standard" complications at 4.5% (21/465). There was no statistical difference regarding tumor thickness, the location of primary (upper extremity vs trunk), average number of sentinel nodes removed, positive SLNB rates (10% vs 12%), patient age, or gender. All cases of AWS solved with expectant management; none required surgical intervention. We detected only one case of AWS in our series.

Other, rare, systemic reported complications were detected in 26 cases (0.29%) in the meta-analysis[20], and included :

Allergic reactions to sulfan blue dye reportedly appear in approximately 1.5% of cases, although most are mild allergic reactions. A systematic review[32][33] A of reports of anaphylactic responses to isosulfan blue dye and patent blue V dye during SLNB for any tumor, reported that incidence of anaphylaxis varies between 0.06 and 2.7%, with a mean value of 0.71%.

Trials for measure this complication are mainly focused in breast cancer patients. In the ALMANAC trial[33], the authors reported minor reactions after blue dye injection in 51 of 5853 (0.9%) SLNB procedures. Severe allergic reactions, requiring administration of a vasopressor or a change or cessation of the procedure occurred only in 4 of 5853 (0.07%) procedures. In NSABP B-32, allergic reactions secondary to blue dye occurred in 0.7% (37 of 5588) of patients for whom data on toxic effects were available[34]. Anaphylactic shock after administration of blue dye for SLNB is potentially lethal and must be considered a medical emergency. Different grades have been described: grade I (allergic skin reaction only); grade II (transient hypotension not requiring vasopressor support); and grade III (transient hypotension requiring vasopressor support)[34]. In some cases, a biphasic anaphylactic reaction has been described, with hypotensive episodes occurring at 15 min and 2 h after blue dye injection[35]. This reaction must be recognized to manage the patient effectively in the post-operative period. As for other authors' knowledge, no cross-reactivity has been described between blue dye and any other drugs. In the same way, there is no test available to predict allergy, because specific antibodies only appear in the event of an anaphylactic reaction and do not exist beforehand.

Meta-analysis of complications of SLNB in melanoma patients detected 13 cases of 'allergy' to the radiocolloid or blue dye, however the term 'allergy' was not often defined, and therefore the true rate of hypersensitivity or anaphylaxis cannot be reported.

Some series described a well-documented inmediate-hypersensivity rash:

Leong et al[36] reported a 1% incidence of anaphylaxis to isosulfan blue dye: 3 cases in a series of 406 melanoma patients during lymphatic mapping.

Lock-Andersen[23] described 2 cases (among 198 patients who underwent SLNB) of universal urticarial rashes, 20-30 minutes after injection of the dye. Vital signs were not afected.

However, SMT[7] not identified any complications directly associated with blue dye in >2100 cases. Multicenter Selective Lymphadenectomy Trial-1 (MSLT-1)[9] found allergic reactions (0.17%) but not cases of anaphylaxis. We could not measure this specific complication given that blue dye was not used in our centre.

In a series of SLNB for breast cancer[37], intradermal injection of methylene blue dye caused skin lesions at the injection site, which was avoided using deep breast parenchymal injections. Because SLN mapping for melanoma surgery involves a more superficial injection, use of methylene blue dye in this setting carries a relative contraindication unless overlying skin is being excised where the injection took place.

Extremely infrequent complications included urinary complications (five patients), deep vein thrombosis (four patients), myocardial infarction (two patients), pulmonary embolism (one patient) and cerebral vascular accident (one patient). There were no deaths secondary to SLNB reported. None of our patients suffered these serius, systemic adverse events nor anaesthetic complications.

What are the expected or acceptable complication rates for SLNB?

At present, there is no consensus on surgical performance indicators and complication rates in melanoma surgery. Consequently, there are no standards with which individual surgeons and units can compare their own audited outcomes. Surgical standards published in 2008, following a review of the literature and expert opinion, proposed a threshold of <5% for SLN site infection or seroma requiring aspiration [2]. Our rates of seroma was higher, but it was probably overestimated.

Risk factors for SLNB morbidity

Most studies not include clinically relevant information regarding relationships between complications and patient-specific risk factors for complications. Identification of such risk factors may ultimately allow for a reduction in complications[8].

Age

We did not find differences in complication rates based on age. Meta-analysis detected that the average age of patients at the time of SLNB was presented only in 17 studies and age at melanoma diagnosis in two studies. Therefore, no accurate comparison or conclusions can be made regarding the age of the patients and complication rates[20].

Nodal basin

In our series, the location of the primary melanoma and lymph node basin are the two factors significantly related to a higher risk of complications. As we previously mentioned, a significantly increased rate of complications with inguinal nodal basins compared with cervical or axillary nodal basins was detected in the literature. In the meta-analysis[20], the percentage of complications reported in each lymph node basin was extractable only from 10 studies [5][7]

[8][10][22][29][38][39][40][42] (Table 3). Overall, there were 257 complications reported in 3541 biopsies. With respect to lymph node basin, there were 118 complications in 1922 axilla biopsies; 110 complications in 992 groin biopsies; 21 complications in 594 neck biopsies and eight complications in 73 'other' site biopsies. Separate pooled estimates were figured for the rate of complications per lymph node basin site in order to identify any significant differences. The site with the highest incidence of complications was the groin with a rate of 14.9% (95% CI: 6.1-26.7), followed by the axilla at 9.8% (95% CI: 4.7-16.6). The neck had the fewest complications with a rate of 5.1% (95% CI: 2.2-9.3). There was no significant difference in complication rate between the lymph node basins .

At least two studies[12][39] found that the more SLNs removed, the greater the risk of complications at the SLNB site, but differences were not statistically significant. Wasserberg et al[29] demonstrated not only that number of excised nodes was significantly associated with an increased rate of total complications, but also that it was the only independent factor to predict them (2 nodes, sentinel or other) (p=0.007). Sampling of more than one basin site did not affect morbidity. One year later, Roaten et al[8] showed that patients having 2 nodes (n = 107; 7.5%) or 3 nodes (n = 62; 11.3%) excised at SLNB were at significant higher risk of complications than those patients having a single node (n=156; 3.2%) excised at SLNB (p = 0.02). We could not find this trend in our series.

Comorbidities

As we previously commented, the retrospective design of the study did not allow reaching a conclusion about comorbidities and SLNB complication risk.

Ling et al[38] studied the relation between complication rate and being overweight. The mean weight for those who developed a complication was significantly greater than that for those without complications (91.9 kg vs 78.6 kg, P = 0.03). Likewise, the mean body mass index for those with complications was greater compared with those who did not develop a complication (31.04 vs 27.29, P = 0.05) We did not gathered weight nor body mass index in our study. They also detected that not increase the risk of a complication was related to age the type, level or thickness of the primary melanoma, smoking, alcohol, diabetes mellitus nor use of aspirin or warfarin. The use of intravenous intra- operative or post-operative oral antibiotics did not significantly decrease the risk of a complication (P-values 0.34 and 0.63 respectively). However, other authors[13][42] detected an increased risk of complications associated to smoking.

Roaten et al[8] identified 16% of patients with preoperative comorbidities including diabetes, obesity, cardiac disease, or a history of smoking. They showed no significantly increased risk for complications (9.3% vs 5.2%).

Ascha et al[41] used the National Surgical Quality Improvement Program (NSQIP) database to explorate predictors of 30-day readmission for surgical complications of SLNB and CLND. Of 3006 patients included, 151 (5.0%) returned to the hospital. No significant differences were found between readmission rate of CLND patients (5.3%, 65/1235) and SLNB patients (4.9, 86/1771). Predictors of hospital readmission were smoking for overall SLNB and cervical SLNB on multivariate analysis, age for cervical and inguinal CLND, and hypertension for cervical CLND. Diabetes, preoperative hematocrit and male sex were predictors for inguinal SLNB. There were no significant predictors for axillary SLNB nor overall CLND procedures.

The median follow-up for our study was 46 months, and we believe that most late complications like lymphoedema, hypertrophic/painful scars or chronic seroma were captured during this follow-up period. The minimum follow-up was extracted in the meta-analysis[24] from the data reported in 12 studies, ranging from 11 days[23] to 12 months[42][43], although the study[23] with 187 patients, reporting a minimum follow-up of 11 days, did have a mean follow-up period of 24 months. Althought most were early operative complications, some late complications could be missed because they become apparent during more extended follow-up periods. Several articles report complete resolution of complications within the follow-up period[3][8][44][45]. One study[46] reported that 3% of their patients had 'permanent' lymphoedema and two papers[23][39] reported two cases of persistent staining from the blue dye. However, most of the studies partially reported or failed to report whether or not the complications had been resolved. In our series, lymphoedema was not completely solved at the end of follow-up.

Technical aspects of surgery

No differences among specialities were detected in our study. We could not find previous studies that compare the risk of complications

Table 3 Distribution of nodal basin sites in SLNB and complications (percentage of complications for each location).

Series/Nodal basin	Neck	Axilla	Groin	p
Theodore et al [5]	-	5%	14%	0.0001
Wrightson et al [7]	2.4%	4.4%	8.1%	-
Roaten et al[8]	3.6%**	4.8%	5.3%	>0.05
Jørgensen et al [10]	-	10%	24%	-
Cigna et al [22]	2.6%	6.9%	4.4%	-
Wasserberg et al[30]	8.5%	17.1%	28.2%	0.001
Ling et al[39]	0%	31.2%	68.8%	0.04
Hettiaratchy et al[40]	19%	22%	41%	<0.04*
Verdier et al[41]	17%	17%	32%	-
Persa et al[42]	-	33.9%	66.1%	<0.0001
Total(21)	5.1%	9.8%	14.9%	>0.05
Our series	13.6%	17.8%	31.3%	0.03

considering type of surgeon or ambulatory versus hospital-based surgery.

There are controversial results with regards to the surgeon's experience: one study[39] observed that complication rates not decrease with experience (increasing patient numbers) after learning curve. Another one[8] found that incidence of annual complications inversely correlated with the cumulative number of SLNBs performed during this period.

Stoffels et al[47] compared morbidity of SLNB performed under TLA (tumescent local anaesthesia) or GA (general anaesthesia). No major complications like lymphoedema or vascular injuries or nerve damage occurred. There was no operative death. Twenty- two of 300 (7.3%) patients had one minor complication. The rate of complications was 6.2% (13/211) in the TLA group and 10.1% (9 / 89) in the GA group. The operating times between the TLA group and the GA group were comparable.

Roaten et al[8] detected that use of closed-suction drainage was associated with a higher incidence of wound-specific complications (13.2% vs 2.2%, $p < 0.001$), whereas some authors not found association with the use of drain tubes[38]. The retrospective nature of this study makes it impossible to discern whether there is a real causal relationship between closed-suction drainage and complications. It may be that the use of closed-suction drains is a surrogate for another variable related to complications from SLNB, such as the extent of dissection.

Rødgaard et al[42] compared the risk of postoperative complications when lymphoscintigraphy was performed 24 hours prior to SLNB with delayed static imaging and with early dinamic imaging, when it was performed on the same day. Surgical morbidity was nearly the same in both procedures.

Regarding geographic variations in surgical procedure, a meta-analysis[20] found no statistically significant difference for complication rates across the different continents. Europe had the highest percentage of reported complications at 12.0% (95% CI: 8.3-16.4), followed by USA with 10.9% (95% CI: 1.9-26.0) and Australasia had the fewest at 5.4% (95% CI: 0.1-17.7). There was only one study from Asia; therefore, it was not included in the pooled proportion analysis.

Conclusions

SLNB was introduced as a minimally invasive procedure to provide valuable information regarding the regional spread of melanoma. It was initially regarded as a means of avoiding unnecessary ELND, which are associated with significant morbidity. However, not all publications associated with SLNB make reference to complications or morbidity.

The role of SLNB is becoming increasingly controversial in patients with melanoma, because MSTL-2[50] concluded that there is no final proof that SLNB influences their overall survival. This limited therapeutic benefit makes the need for a highly accurate technique with no significant side effects.

Our study supports historical data that SLNB is a low-risk procedure. The key findings of this analysis about patients who underwent SLNB in a single AMS unit include a low average complication rate of 22.1% (being the most commonly reported minor and early post-operative complications) and absence of intra or post-surgical mortality, life-threatening local complications and differences among surgical specialities. Readmission was required only in 2.6% of cases, mostly due to infection-related cases circumstances that needed intravenous antibiotics. The location of primary melanoma and lymph node basin were significantly related to higher risk of post-operative complications.

Similar to other authors[17], we consider that further multi-centre and prospective studies with accurate and uniform definitions of complications are needed to collect comparable data Also, the standard way to report the timing of complications is required, in order to allow analysis of early and the timing of reported complications needs to be more commonly reported to enable the study of early and late morbidity. The solution could be to counsel patients before the procedure, and to aid surgeons in assessing their practice.

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