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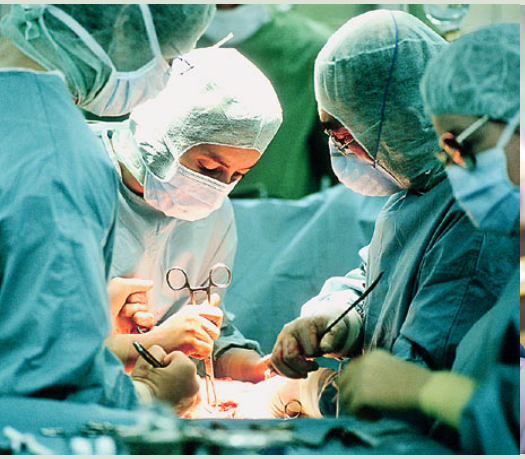
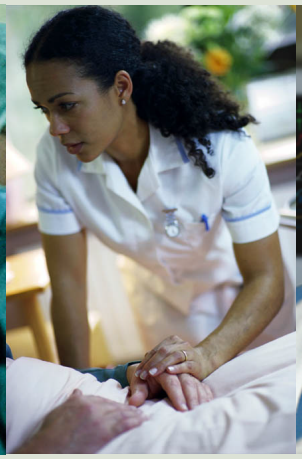

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Contents

Day Surgery Data Project

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Abstract

Day surgery (DS) development represents a priority being an important opportunity for health systems reorganization. Strong evidence suggests that DS is the best option for 80% of elective surgical operations providing a safe, high quality and cost-effective approach. There is great potential for further expansion of DS in Europe.

Available DS data and indicators present important constraints hindering DS growth and development. The general objective of the project is to validate and define a set of DS standard indicators and, more generally, to develop the information systems on DS in Europe. It will also identify and test potential indicators.

Main methods and means will include the review of existing DS indicators at international level and the assessment of DS data and indicators in participating member states (MSs). Most promising candidate indicators will be empirically tested through a pilot study in a selected group of participating MSs. Comparability of data will also be ensured through recoding of DS procedures. A minimum and ideal list of indicators will be constructed on the basis of a literature review and results of the pilot study. The project will also devise guidelines for the presentation, interpretation and utilization of indicators.

The project will work in strict collaboration with European Community Health Indicators and other relevant European initiatives in the area of health information systems. The project's strategies and results will be fully applicable to the European context and congruent with the European Union (EU) effort in developing information and knowledge systems.

The expected outcome is a streamlined and standardized DS information system integrated into the EU indicators framework, used by health care policy-makers, DS managers and providers to expand DS and continuously improve its quality, efficiency and equity. A streamlined DS information system represents one of the most important preconditions for improving whole DS systems and their components, such as a network of DS clinics.

Key words: Health information system, health indicators, day surgery, ambulatory surgery.

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Associated Partners: National Institute for Health and Disability Insurance, Belgium; Association of Danish Regions, Denmark; Caisse Nationale d'Assurance Maladie Travailleurs Salariés, France; Europ-Med Medical Company, Hungary; Agenzia Nazionale per i Servizi Sanitari Regionali, Italy; Azienda Ospedaliera di Padova, Italy; Centro Hospital do Porto, Portugal; Emergency County Hospital, Romania; Orebro University Hospital, Sweden, and King's College Hospital, United Kingdom

Collaborating Partners: International Association for Ambulatory Surgery

Project's Rationale

European healthcare systems confront several important challenges, in particular an aging population, the adoption of costly technology, an increasing expenditure above inflation together with shrinking resources and unequal access and quality of services. Some systems experience even tougher choices given a sluggish economy and a health system infrastructure mainly based on large hospitals.

In response to such a context, policy-makers must take strategic decisions capable not only of controlling health-related costs, but above all gaining efficiency, both allocative and operational. Policies also must ensure a good and continually improving quality of health services in all its dimensions, i.e. effectiveness, safety, access and citizens' satisfaction. In addition, policy-makers must guarantee that different population groups have equitable access to services of similar quality and contribute their fair share to its financing.

Another challenge originates from the implementation of policies, making sure they do not remain just good intentions or, worse, produce unintended consequences, and are transformed instead into programs and practices. Increasingly in the future EU health systems will face an ethical dilemma regarding how to assure sustainable and equitable access to effective and safe procedures. The design and implementation of DS systems based on valid and reliable evidence will contribute to the solution to the above mentioned issues.

In most developed countries DS is now considered the best option for 80% of elective surgical operations providing a safe and effective approach. DS rather than inpatient surgery, is increasingly being considered the norm for all patients undergoing elective surgery (NHS Modernisation Agency 2004), rather than simply an alternative form of treatment for a few. The rationale for DS is that it is as safe, if not safer, and of the same quality as those procedures done as inpatient surgery (Policy Brief "Day Surgery Making it Happen", European Observatory on Health Systems and Policies with the collaboration of IAAS, 2007).

Although there are very few clinical trials comparing traditional inpatient and DS, those that have been undertaken show no significant difference in outcomes (Castells et al. 2001; Corvera et al. 1996;

Dirksen et al. 2001; Fedorowicz et al. 2005; Hollington et al. 1999). These, along with a number of non-randomized studies, demonstrate that DS is a safe approach when all the recommended guidelines and organizational principles of a DS programme are followed. Mortality and major morbidity directly associated with DS is extremely low (<1%) (Lemos and Regalado 2006; Shnaider and Chung 2006). Unplanned return visits to hospital and re-admissions within 30 days directly related to day surgery procedures range from 0.28% to 1.5% (Coley et al. 2002; Mezei and Chung 1999; Twersky et al. 1997). Unplanned admissions following surgery can be decreased through the use of appropriate clinical pathways, with one study finding that pathway implementation was associated with an increase in same-day discharges from 21% to 72% and a steady reduction in unplanned postoperative admissions as experience with the pathway increased (Calland et al. 2001).

The peer-reviewed and grey literature show that in most EU contexts DS is not used to its full potential, as shown, for example, by the results of a recent survey conducted by the International Association for Ambulatory Surgery in 19 countries. Another study shows that the percentage of hernia repairs performed as day cases by MSs health services varies between 6 and 73%. The same investigation reveals that the percentage in the USA is almost 90%. Similar variability is apparent for other common procedures like cataract removals. Again the EU is lagging behind the USA and, in this case, Canada too.

Wide inconsistencies concern not only output measures but also policies, strategies, practices and, presumably, outcomes within the same nation and among countries. The incompleteness and unreliability of available data concerning DS in Europe makes the problem more complex. For example, there is ambiguity about data definition (e.g. ambulatory surgery vs DS vs outpatient surgery), discrepancies in databases content and disagreement on the basket of procedures to be monitored. Very little is known about the gender and ethnic perspectives applied to DS services. The evidence regarding this strategic issue for the health sector in Europe is thin and this limits evidence based decisions.

Reliable, accurate, timely and relevant information represents the basis on which knowledge can be generated and sound decisions made at all levels, i.e. strategic, managerial and operational. This project intends to analyse and then streamline and standardize existing data and health indicators on DS. More broadly, the project will strive to make sense of the knowledge produced and share the lessons learned among all MSs and beyond. The project's strategies and results will be fully applicable to the European context and congruent with the EU effort in the development of information systems.

DS represents an innovative tool for health sector reform in Europe contributing to several common objectives such as improving quality of care, controlling cost, enhancing efficiency and possibly equity. Up to now efforts to promote DS in MSs and Europe have been rather patchy, lacking a strategic perspective. One of the reasons behind such a situation is the paucity of indicators and knowledge concerning critical aspects of DS organization and performance, e.g. systems of incentives for providers, outcomes for different procedures and gender issues. A state of the art DS information system will also improve the accountability of clinicians, managers and policy-makers. This aspect fully matches current dominant values and concerns regarding transparency about policy effects, managers capability and providers competence.

Aim and General Objectives

This project aims at closing the gaps in data, information and knowledge concerning DS in Europe. Such knowledge will be invaluable for an evidence-based design of DS systems of care. The project will recommend a coherent set of strategic and operational options which will help the design of a streamlined and standardized DS information system in Europe.

This initiative will also explicitly suggest how to bring DS indicators together under an overall framework and address specific actors playing various roles at international, national, regional and services delivery level. The new knowledge will help the formulation and implementation of technically effective, managerially sound, economically sustainable, socially acceptable and equitable DS systems of care in Europe. The indicators will also allow the monitoring and evaluation of current and future strategies and programs and the comparison within the same nation, its regions, and among different MSs. All this will make DS continuous improvement possible. More generally, analyses and recommendations resulting from this project will be relevant to day hospital systems in Europe.

The general objectives of the project are to identify and validate a set of DS indicators and to develop the Health Information Systems on DS in Europe. The recommended set of indicators will comply with the following criteria: reliability, validity, standardization, comprehensiveness, relevance to different users and innovativeness. The standardization of a DS information system will make comparisons among DS managed by different MSs credible. The DS information system will allow the measurement of the effects of policies, i.e. broad aims, strategies, i.e. means to achieve those aims, and programs, i.e. set of resources and activities contributing to the aims, on DS quality, productivity, efficiency and equity. Equity refers to the similarity in the allocation of healthcare resources, access to services and effects on health status among different socio-economic groups.

The project proposes to review the DS indicators available within EU health information projects and other international organizations. It also intends to conduct a thorough analysis of participating MSs DS data and indicators. The enquiry on DS data and information will allow the detection of gaps, opportunities and discrepancies among international organizations and MSs. In addition this initiative intends to test new potential DS indicators especially in the area of effectiveness.

Furthermore the project will contribute standard definitions of key data, practical steps making databases more homogeneous and linkable, standard description, sources and procedures to compute indicators, and reach consensus on a minimum and an ideal set of DS indicators to be recommended for use at EU, MSs and regional levels. The project intends to integrate the standardized DS indicators in the European Community Health Indicators (ECHI). Close coordination with current and completed projects with similar goals will prevent potential overlaps and waste.

In order to assure its integration in the growing European information and knowledge system, the project will work in strict collaboration with ECHI and other relevant European initiatives from its earliest phase.

Strategic Relevance

There is great potential for further expansion of DS in Europe and its development represents an important opportunity for health systems' reorganization. A recent survey showed wide discrepancies in the adoption of DS among different countries: the percentage of appropriate interventions carried out by DS services showed variation ranging from less than 10% to around 50%. In advanced countries DS is now deemed the best option for about 80% of elective surgical operations.

As a result a DS System represents a crucial opportunity for the reorganization of health services. Such a system can contribute to several key goals pursued by the health sector in Europe: cost control, greater productivity and efficiency, enhanced quality and possibly improved equity. More specifically, DS allows cost cutting, for example through beds and staff reduction, and increases productivity through better scheduling and faster throughput of patients. DS fosters allocative efficiency so that resources are apportioned in a way that maximizes the net benefit attained through their use. DS also enhances operational efficiency, i.e. the proper combination of people, process, and technology coming together to enhance the productivity of surgical services. Without compromising effectiveness, DS can improve safety, e.g. reducing hospital infections, expand access, e.g. shortening waiting lists, and enhance patient satisfaction, e.g. avoiding stress derived from overnight hospitalization. Therefore DS can have a positive impact both on citizens' health status and their satisfaction with service delivery. DS development can also convert into more equitable services both in terms of safety and access.

This Project intends to offer a contribution towards the attainment of the objectives of the Second Health Programme, i.e. first and foremost to generate and disseminate health information and knowledge and, secondly, to promote health, including the reduction of health inequalities.

Participating MSs comprise distinct religious and cultural traditions, face dissimilar economic maturity and have diverse levels of prosperity and equity in the distribution of wealth. Participating nations have disparate populations and size, are located in every major area of Europe: north (e.g. Sweden), south (Italy), centre (France), east (Hungary) and west (Portugal). Furthermore, their institutional integration in the EU varies because some have recently joined the EU and some others are funding MSs. The Project will also investigate DS services through the gender perspective, looking, for example, at possible differences in DS services utilization by gender. The wide representation of countries participating in the Project will make the diffusion of its recommendations among all MSs easier. At the same time, the relatively limited number of involved MSs will facilitate a smooth management of the project.

Methods

The review of existing DS indicators at international level and the assessment of DS data and indicators in participating MSs will be carried out on the basis of research protocols designed by representatives of the national associations for ambulatory surgery who are also members of the Executive Committee of the International Association for Ambulatory Surgery (IAAS). The IAAS is made up of 23 national ambulatory surgery associations and is the only organization specifically dedicated to the development of high quality ambulatory surgery across the world. These professionals comprise the best expertise in the field. The research protocol will adapt objectives and methods used by Caisse Nationale d'Assurance Maladie des Travailleurs Salaries in a study on ambulatory surgery in France. The EU health indicators framework will provide another important background.

The evidence regarding existing gaps in DS indicators at international and MSs level accompanied by a review of the literature will identify potential indicators. Those deemed most promising candidates will be empirically tested through a pilot study in a selected group of participating MSs. From a scientific viewpoint, such investigation will represent the most challenging phase of the project because it involves linkages among databases, analysis of reliability and validity and building probabilistic models, specifically multiple logistic regressions.

Standardization of DS data and indicators at MS level represents a prerequisite for comparing the outputs and effects of different policies and programs. A list of basic definitions of DS will be drawn in accordance with the "IAAS Suggested International Terminology and Definitions", the definitional framework used in the International Compendium of Health Indicators (ICHI) and in the OECD System of Health Accounts (SHA). Comparability of data will also be ensured through a recoding of DS procedures. The minimum and ideal lists of indicators will be constructed on the basis of a literature review, in particular the set of indicators recommended by the IAAS, the French and Australian clinical indicators and the EU health indicators framework and the results of the pilot study.

The project will devise a strategy to ensure coordination with European Community Health Indicators Phase 2 and an integration of the recommended lists of DS indicators into the EU framework indicators and MSs health information systems.

Most of the methods, analyses and results of this project will be easily reproduced by international, national and local health administrations not involved in the initiative. Rather complex methods, such as the creation of mathematical probabilistic models, e.g. multivariate logistic regressions, may be developed by national agencies or with the help of local universities. The analysis and interpretation of the inverse association between volume and outcome, equity of access and of outcome and size of catchment areas are straightforwardly reproducible to fit different geographical areas.

The project will be led by a Scientific Committee (SC) consisting of one representative for each associated partner and five representatives from the Collaborating Partners. The technical activities will be carried out by Working Groups consisting of experts in Day Surgery, biostatistics, epidemiology and public health. For the evaluation of the project, the SC will be assisted by an Assessment Group. The SC will be assisted by an Expert Team consisting of one international expert in epidemiology/public health and one international expert in biostatistics.

Expected outcome

The expected outcome is a streamlined and standardized DS information system integrated into the EU indicators framework, used by healthcare policy makers, DS managers and providers to expand DS and continuously improve its quality, efficiency and equity. A streamlined DS information system represents one of the most important preconditions for improving whole DS systems and their components, such as a network of DS clinics.

Dissemination

The dissemination plan foresees

- the implementation of the official project web-site offering relevant information about the project and its development, as well as the main outputs;
- presentation of intermediate and final results of the project on the IAAS (www.iaas-med.com) as well as on the partners' websites.

The dissemination will be co-ordinated by the main partner, who is in charge of the implementation and updating of the website. The associated and collaborating partners will co-operate in the dissemination among the national institutions. Finally, all the partners will promote the project and its results among the stakeholders in their own country and provide information to any institution or individual requesting it.

Venous thromboembolism risk stratification and thromboprophylaxis with low molecular weight heparin in patients undergoing major ambulatory surgery: an observational prospective study

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Abstract

Aim: Although supposedly low, the risk of venous thromboembolism (VTE) after major ambulatory surgery (MAS) remains to be established. We have carried out a prospective validation of the risk stratification of VTE in MAS patients.

Methods: 402 consecutive patients were stratified according to a Spanish consensus as: a) no risk of VTE (n=141), b) moderate risk (n=228), and c) high risk (n=33). The moderate and high risk groups received thromboprophylaxis with low molecular weight heparin. On post-operative day 10, a colour Echo-Doppler was obtained; on days 10 and 30 different parameters of efficacy and safety were measured.

Results: 357 patients completed the study. No symptomatic events were observed; one case of asymptomatic deep vein thrombosis was observed. Overall, in 39 patients (three from the low risk group and 36 in the moderate and high risk groups; $p<0.001$) a decrease to 15 cm/s was observed in interior femoral blood flow. Haemorrhagic complications, all of them minor, in the surgical wound accounted for 2%. The study of thrombophilia revealed a high number of patients with hidden thrombophilia (28.1%).

Conclusion: MAS patients are not free of VTE events and require risk stratification. Thromboprophylaxis with LMWH in moderate and high risk of VTE is safe and effective.

Keywords: Major ambulatory surgery; Day case surgery; Venous thromboembolism; Deep venous thrombosis; Risk stratification; Antithrombotic drugs; Low molecular weight heparin; Bemiparin

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Introduction

Venous thromboembolic disease (VTE) is a well known pathology with many repercussions, whose preventive aspect (recommendations) is fairly well established in the field of non-ambulatory surgery [1,2].

Major Ambulatory Surgery (MAS) is now in its maturity and is widely used. Its special characteristics differentiate it from what could be considered traditional surgery, and currently nobody questions its efficacy and safety, although the need for certain actions used in conventional surgery, such as antithrombotic therapy, has been widely debated. In this sense, very few works have been published and there are almost no specific orientations regarding thromboprophylaxis within the field of MAS [3,4]. As a result of the paucity of specific guidelines concerning thromboprophylaxis, there are some variations in clinical practice.

In light of the foregoing, in Spain a panel of experts was created with a view to gaining consensus from the available information about thromboprophylaxis in MAS [5]. The aim of the present work was thus to validate the recommendations made by that panel for MAS procedures in general surgery. In particular, our aims were: a) to confirm the existence of different groups at risk of VTE in MAS (risk stratification) and b) to assess the effectiveness and safety of a low-molecular weight heparin (LMWH) administered in the post-operative period for the prevention of thromboembolic events after general MAS surgery in moderate and high risk groups.

Materials and Methods

The study included 402 consecutive patients who agreed to participate (written consent) in a prospective observational clinical study. The patients were undergoing MAS procedures at the University Hospital in Salamanca (Spain) along a period of 20 months (2007–2008). All interventions were carried out by the same surgical team: two highly experienced senior surgeons.

Basal determinations

Before surgery, the following actions were implemented: a) collection of the clinical history of each patient, placing special emphasis on a previous or family history of thrombosis; b) randomization, for the search for thrombophilia in one third of the patients; c) assessment of the thromboembolic risk of each patient; on stratifying risk, the type of thromboprophylaxis was determined automatically.

Thromboembolism risk stratification

The risk of VTE was determined following the guidelines of the 2006 Spanish Consensus Conference [5]. The combination of surgical (A) and personal (B) risk allowed the patients to be classified in

Table I Evaluation of the risk of VTE and proposal of thromboprophylaxis*.

A. Surgical risk factors	B. Personal risk factors	Risk of VTE	Proposal of prophylaxis
Low	I	No risk	Only physical measures
	2	No risk	Only physical measures
	3	Moderate risk	+ LMWH moderate dose
Moderate	I	Moderate risk	+ LMWH moderate dose
	2	Moderate risk	+ LMWH moderate dose
	3	High risk	+ LMWH high dose
High (No MAS)	I–4	No MAS	

A. Surgical risk factors

Low risk	Moderate risk
Laparoscopic surgery < 60'	Laparoscopic surgery > 60'
Abdominal wall hernias (unilateral)	Abdominal wall hernias (bilateral)
Cholecystectomy	
Perianal surgery	
Extensive soft parts surgery	

1= minimum

2 = low

3 = moderate

4 = high (not candidate for MAS)

B. Personal risk factors

Level 2 (low risk)	Level 3 (moderate risk)
Age < 40 years	Age > 40 years
Pregnancy. Puerperium. Estrogens. Contraceptives	History of VTE
Cardiorespiratory insufficiency	Active neoplasm; chemotherapy
Varicose veins	Chronic myeloproliferative syndrome
Inflammatory intestinal disease	Nephrotic syndrome
Obesity (BMI >30%)	Congenital and acquired thrombophilia
Chronic smokers	Paralysis of lower limb
Orthopaedic surgery of lower limb	
Immobilisation	
Length of surgery < 30 min.	

two groups (Table 1); without risk of VTE, and hence not requiring LMWH, and with the risk of VTE, for whom the administration of LMWH is considered. The latter patients were subdivided into moderate and high risk individuals.

Thromboprophylaxis

All patients were recommended (in oral and written form) to walk actively every day from the day after operation. No elastic stockings were recommended or prescribed. Selectively (depending on the level of risk), Bemiparin (Hibor®, Laboratorios Rovi SA, Madrid, Spain) was administered subcutaneously at doses of 2,500 IU/24 h or 3,500 IU/24 h (the latter in the high risk cases), starting 6 h after the end of surgery and lasting 7 days. Although Bemiparin does not have contraindications at moderate prophylactic doses, in the case of high doses the following were taken into account: platelet count <50,000 mm^3, severe renal impairment that would require monitoring, and active gastro-intestinal ulceration. It was recommended that the point of subcutaneous injection of the LMWH should be as far away as possible from the surgical wound.

Study of thrombophilia

Owing to economic problems, this study was only performed in one third of the patients (pre-operative blood extraction). To accomplish this, a table of random numbers compiled at the start of the study was used. The results were not made available until the final evaluation of the data and hence were not taken into account on assessing the pre-operative risk of VTE and performing the stratification. Indeed, the aim of the study of thrombophilia was precisely to determine how this parameter would influence the stratification *a posteriori* without knowledge of such results (*a priori*).

The following determinations were made: levels of antithrombin-III, protein C and S, presence of Leiden Factor V and FII20210 of prothrombin, levels of homocysteine and determination of Methylene-Tertrahydrofolate-Reductase (MTHFR). Likewise, the existence of resistence to Active Protein C (R-APC) (not Leiden Factor V) was determined. The following were considered pathological: antithrombin-III deficit (< 80%) deficit in protein C and S (<60%), R-APC< 2.5 and hyperhomocysteinaemia > 15 µg/dL.

Follow-up

In all patients, regardless of their risk group, different controls were performed at 10 and 30 days after the surgical procedure. On the 10th day, the following were explored:

1) clinical assessment, searching for symptomatic thromboembolic events and complications derived from the administration of the LMWH, mainly ecchymosis at the injection site and haemorrhages (zone and amount);
2) degree of compliance to the prophylaxis (adherence to the LMWH regime) by the patients at home;
3) degree of difficulty involved in the administration of the LMWH;
4) acceptance of the prophylaxis (LMWH) by the patients;
5) Colour Echo-Doppler of the superficial and deep venous systems of both lower limbs, and
5) CT (only in cases of clinical suspicion of pulmonary embolism). At 30 days: a) clinical assessment of thromboembolic events (between day 10 and 30), and b) study of morbidity and mortality.

Echo-Doppler

On day 10 after surgery, a colour Echo-Doppler (ED) study was performed to establish the presence of deep or superficial venous thrombosis When there were doubts about the diagnosis in the first

exploration, a second ED was obtained 7 days later. The study was carried our by two expert sonographists, who were blind in the sense that they did not know which risk groups the patients belonged to.

A Toshiba Aplio XG™ with a multisequence linear probe was used. A frequency of 7.5 MHz was employed for the inguinal, thigh, and popliteal zone. Frequencies of 9–10 MHz were used for the great saphenus vein, with variations in both sectors, depending on the body mass index of the patient.

With the patient in the supine position, transverse and longitudinal images of the common femoral, femoral and popliteal veins of the deep venous system and of the great saphenous vein in proximal sectors until the crook of that vein was obtained in mode B in both lower limbs. Compressions were consistently made in all these venous sectors until total collapse of the lumen.

Following this, spectral flow images were obtained in both common femoral veins, placing special emphasis on the morphological aspect of the wave, together with measurements of flow rate in those locations. To obtain the venous spectrum and velocity in both common femoral veins an attempt was made to modify the incidence of the beam until an angle between 30 and 60º was achieved, adjusting the PRF (Pulse Repeat Frequency) to the minimum possible in order to avoid artefacts due to "aliasing". After correcting the angle, a measurement was obtained in the highest region of the curve that corresponded to the expiratory phase when venous return is favoured [6].

With the measurement of venous flow and diameter at the level of the common femoral vein peak blood velocities (cm/sec) and cross-sectional area (cm^2) [7–9] were calculated, which are accepted parameters for the measurement of a pre-thrombotic state characterised by venous stasis [10].

The second echographic assessment, carried out one week after the first one and after continuing treatment with LMWH (in the cases in which it was being administered), was performed when flows of less than 10 cm/s were detected or when flows were below 15 cm/s with alterations associated with the morphology and the spectral trace (mainly the loss of fascicity) or when mobile internal echoes were detected in mode B echography with flows not clearly detectable by the colour Doppler.

Statistical study

Using the Filemaker Pro 8.5 Advanced database, we compiled a data acquisition document in which we included all the data relative to each patient who agreed to participate in the study and signed the written consent form.

The SPSS 15.0 program was employed to perform the statistical calculations of means and standard deviations, the Chi-squared test, Student's t test for the comparison of means with paired groups on comparing the flows in both limbs in a single individual, or independent groups on comparing the flows in one limb of patients with a low, moderate or high risk of VTE. Statistical significance was set at $p<0.05$.

Results

Of the 402 patients included in the study, 357 (88.8%) completed it. Two patients did not comply to the treatment with LMWH, and in the follow-up 43 patients were lost. Finally, 119 (33.3%) (non-risk group/without Bemiparin) and 238 (66.6%) (risk groups/with Bemiparin) were studied; in the latter group, 30 patients (12.6%) were high risk (Fig. 1).

Table 2 shows the surgical and personal risk factors stratifying the patients within a given risk group.

In the Bemiparin groups, we observed high percentages of a) compliance (adherence to the prophylaxis); b) administration by the patients themselves or a family member (i.e. not requiring health-carer attention) and c) acceptance of the method by the patients (Fig. 2).

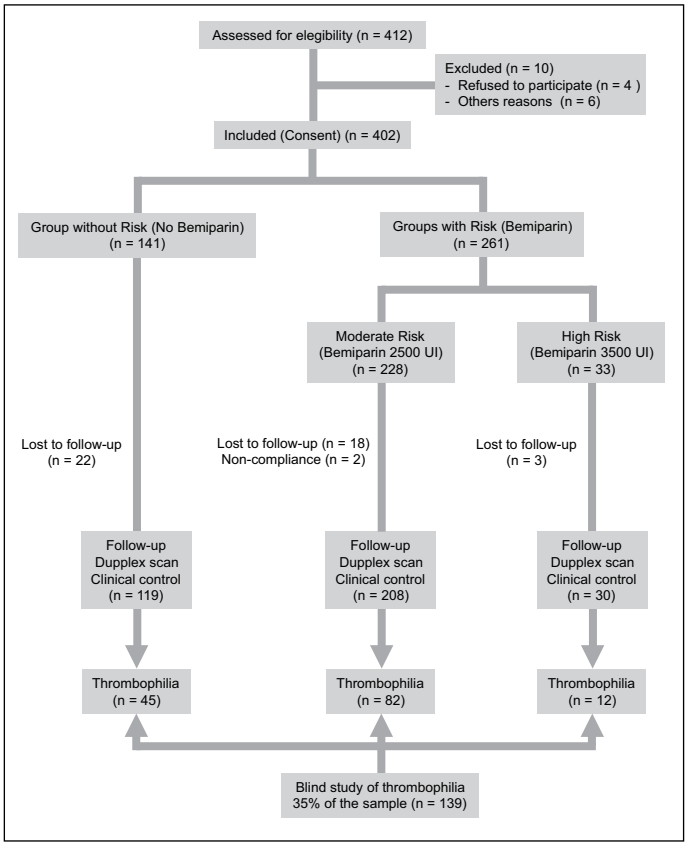

Figure 1 Inclusion, loss, withdrawal and definitive follow-up of patients.

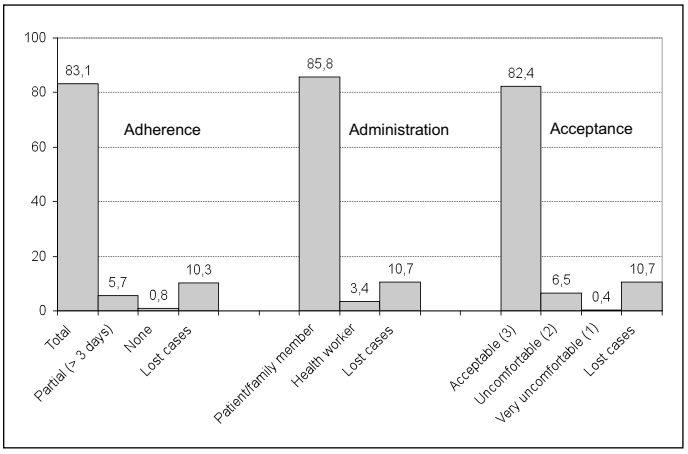

Figure 2 Results (in percentages) of compliance or adherence to prophylaxis, who administered the low molecular weight heparin, and its acceptance by the patient (scale from 1 to 3).

Thromboembolic events

No symptomatic events were observed. We only noted one asymptomatic deep venous thrombosis (femoral vein) in the Bemiparin group (of moderate risk), revealing an incidence of 0.48% (1/208 cases) or 0.28% (1/357) when the whole series was taken into account. No helical TC was performed since no symptoms/signs suggestive of pulmonary embolism were observed during the 30-day follow-up period (Table 3).

Overall, in 39 patients (10.9%) we observed the existence of a decrease in venous flow -lower than 15 cm/sec- in one of the two common femoral veins. This was significantly higher ($p<0.001$) in the risk groups (15.9 and 10%) than in the non-risk group (2.5%). Two weeks after the surgery (according to the second echo-Doppler) all the patients had femoral vein blood flows above 15 cm/s in both lower limbs (Table 4).

Table 2 Risk factors by groups.

	No risk No LMWH N = 14z1	Moderate risk 2500 LMWH N = 228	High risk 3500 LMWH N = 33	Total N =402
Personal factors				
Age (x ± DS)	27.6 ± 7.1	54.5 ± 10.3	54.6 ± 9.6	
< 40 years	141	5*	0	146 (36.3%)
> 40 years	0	223	33	256 (63.7%)
Sex (M/F)	102/39	192/36	33/0	327/75
Type of surgery				
Inguinal hernia:				
Unilateral	59	163	0	222 (55.2%)
Bilateral	0	2	29	31 (7.7%)
Crural hernia	2	14	0	16 (4%)
Umbilical hernia	10	31	0	41 (10.2%)
Epigastric hernia				
Double hernias	0	3	4	7 (1.7%)
SCPSD**	60	4	0	64 (15.9%)
Others	4	4	0	8 (2%)
Type of anaesthesia				
General	47	90	17	154 (38.3%)
Regional	92	135	16	243 (60.5%)
Local /sedation	2	3	0	5 (1.2%)
Length of surgery* **				
< 30 m	141	223	0	364 (90.5%)
> 30 m	0	5	33	38 (9.5%)

* 2 bilateral inguinal hernias, 2 double hernias, 1 previous DVT

** SCPSD = Sacrococcygeal pilonidal sinus disease *** Excluding anaesthesia time

Table 3 Adverse thromboembolic events and haemorrhagic complications by groups.

	No risk No LMWH N = 119 # (%)	Moderate risk 2500 LMWH N = 208 # (%)	High risk 3500 LMWH N = 30	Total N = 357
DVT	0 (0)	1 (0.5)	0 (0)	1 (0.3)
Altered flow (1)	3 (2.5)	33 (15.9)	3 (10)	39 (10.9)
PE	0 (0)	0 (0)	0 (0)	0 (0)
Complications				
Haemorrhage surgical wound*	0 (0)	6 (2.9)	1 (3.3)	7 (2)
Scrotal haematoma**	2 (1.7)	3 (1.4)	1 (3.3)	6 (1.7)
Ecchymosis (2)				
Extensive	-	9 (4.3)	1 (3.3)	10 (4.2)
Minimum***	-	84 (40.4)	12 (40)	96 (40.3)
Allergy (3)		1 (0.5)	0 (0)	1 (0.4)

DVT = Deep vein thrombosis PE = Pulmonary embolism

(1) Venous flow at the level of the common femoral vein < 10–15 cm/s. (2) Site of injection of LMWH

(3) Related to the LMWH

* Did not require transfusion ** No cases required drainage

*** Less than 2 cm in diameter and on only one occasion

The percentage of scrotal haematomas is half of 3.3% if operated inguinal hernias are considered (all were bilateral)

Table 4 Venous flows (measured at the level of the common femoral vein) by groups.

	No risk No LMWH	Moderate risk 2500 LMWH	High risk 3500 LMWH
1st control (N = 39)			
	N = 3	N = 33	N = 3
Pathological flow*	12.32 ± 2.81	10.65 ± 4.12	10.40 ± 3.22
2nd control (N = 39)			
Lower flow**	19.39 ± 9.82	19.39 ± 6.92	17.73 ± 7.46
Higher flow**	22.06 ± 9.29	23.85 ± 21.27	19.96 ± 7.54
1st control (N = 357)			
	N = 119	N = 208	N = 30
Lower control**	28.76 ± 10.88	20.11 ± 7,46	20.10 ± 5.47
Higher flow**	30.35 ± 12.33	21.57 ± 10,36	21.80 ± 9.12

* A flow of < 15 cm/s was measured in at least one common femoral vein ** Taken from one the common femoral veins (left or right)

Haemorrhagic complications

The most frequent complication derived from the administration of LMWH was ecchymosis at the injection site: lowest manifestation 40.3% (<2 cm diameter and on only one occasion) and 4.2% in the more extensive forms. No differences were observed between the two doses of LMWH employed.

The presence of haemorrhage at the surgical wound appeared in 7 patients (2%). Only the patients who received LMWH showed this complication (2.9% and 3.3% in the 2,500 and 3,500 IU Bemiparin groups respectively). The difference was statistically significant ($p<0.001$). None of the haemorrhages was sufficiently important to warrant blood transfusion, although one case required wound drainage and haemostasis.

In contrast, in all three groups the male patients operated on for inguinal hernias developed scrotal haematomas at similar proportions (no Bemiparin and 2,500 and 3,500 IU Bemiparin). None required drainage.

One patient showed intolerance to Bemiparin in the form of cutaneous erythema.

Impact of thrombophilia

Random studies of thrombophilia were conducted in 139 patients (34.6% of the total sample. We found 39 patients (28.1%) with one or more thrombophilic alterations (excluding MTHFR). The most frequent situation, apart from MTHFR (48.6% of the individuals investigated), involved elevated levels of homocysteine (>15 µg/dL) in 12.2% of the patients. The rest (and their division by groups) can be seen in Table 5.

Table 5 Study of thrombophilia by groups.

	No risk No LMWH N = 141	Moderate risk 2500 LMWH N = 228	High risk 3500 LMWH N = 3	Total N = 402
Patients investigated	45/141 (31.9%)	82/228 (36%)	12/33 (36.4%)	139/402 (34.6%)
Patients with thrombophilia*	12/45 (26.7%)	24/82 (29.3%)	3/12 (25.0%)	39/139 (28.1%)
Type of thrombophilia				
AT-III deficit	2	11	2	15 (10.8%)
PC deficit	1	0	0	1 (0.7%)
PS deficit	0	0	0	0 (0)
FV Leiden (+/-)	1	1	0	2 (1.4%)
FV Leiden (+/+)	0	0	0	0 (0)
FII20210 (+/-)	1	2	1	4 (2.9%)
FII20210 (+/+)	0	0	0	0 (0)
R-APC no FVL	3	3	0	6 (4.3%)
Homocysteine	8	9	0	17 (12.2%)
Combinations*	4	2	0	6 (4.3%)
MTHFR (+/-)	20	25	7	52 (37.4%)
MTHFR (+/+)	2	11	0	13 (9.4%)
Total MTHFR	22	36	7	65 (46.8%)

*Excluding methylenetetrahydrofolate reductase (MTHFR) Antithrombin-III deficit (< 80%) Protein C and S deficit (< 60%) Resistance to active protein C (R-APC < 2.5) Hyperhomocysteinaemia > 15 ug/dL **Note:** heterozygote (+/-);homozygote (+/+)

Based on the results on thrombophilia (*a posteriori*), and attending to the consensus that we wished to validate, the patients were transferred from the risk group they had been assigned to *a priori* (without knowing the results on thrombophilia). Thus, the non-risk group decreased when 38 patients were passed to the moderate risk group. Overall, the highest risk increased by 67 when patients from the moderate risk group were transferred to the high risk group (Fig. 3).

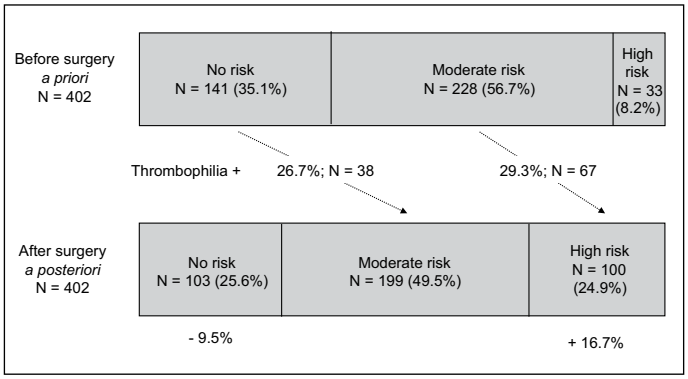

Figure 3 Distribution of the series by risk groups, according to the consensus (Before – *a priori* – and after – *a posteriori* –) knowing the results concerning thrombophilia. It may be seen that the group with no risk decreases while the high-risk group increases.

Discussion

Despite the high frequency and the enormous socio-economic relevance of Major Ambulatory Surgery (MAS), there is a surprisingly small body of information about venous thromboembolism (VTE) in this type of surgery. In fact, only a few consensuses or guides of the many available address the need to identify patients at risk and use thromboprophylaxis in them [3,4]. It should not be overlooked that together with clinical priorities VTE is one of the conditions most frequently involved in medical malpractice suits and the cause of litigation in the United States [11].

The risk of VTE after MAS is not known with precision. Different studies, all of them retrospective [12–15], have reported a low incidence of VTE in patients undergoing MAS. However, four prospective studies that included a systematic screening of VTE (ultrasonography in three, and phlebography in the other) report quite high indices of VTE. Despite this, it is important to note that those studies, included in the excellent review by Ahonen [16] refer only to knee arthroscopy.

It is true that MAS usually involves less invasive surgical techniques and is of shorter duration, implying faster patient recovery. Notwithstanding, it is also the case that patients undergoing MAS are increasingly older, with greater co-morbidity, and that young patients with the risk of VTE must also be addressed [16,17]. Moreover, anaesthetic techniques have been improved and, as seen in our series, regional techniques have gained considerable ground over general anaesthesia. Although the implementation of neuroaxial anaesthesia has a protective effect against VTE [18], this technique, together with the outpatient context of MAS, may hinder or compromise correct application of thromboprophylaxis. In fact, the combination of neuroaxial anaesthesia and antithrombotic drugs makes it necessary to use safety intervals during MAS; these are well known and have been perfectly established in the medical setting [19].

Although based on retrospective studies, a low incidence of VTE has been reported for surgery of inguinal hernias and other interventions in the abdominal wall [12,14]. However, since hernia surgery is one of the most frequent surgical procedures [20] there must necessarily be patients at risk of VTE. It is well known that effects (benefits/risks) and costs are maximally optimized when patients are well stratified.

Just as there is little information about the risk of VTE in MAS, there are also very few studies investigating thromboprophylaxis in MAS, especially if they do not address orthopaedic or laparoscopic surgery [1,4,16,21–24]. Thus, in the meta-analysis carried out by Mismeti et al [25] on low-molecular weigh heparins (LMWH) in the prophylaxis of VTE in general surgery, none of the 59 clinical trials selected by those authors involved MAS. The same is the case of a later review on LMWH in the prevention of VTE after abdominal surgery [26].

Indeed, we are unaware of any randomized and controlled clinical trial that reports the value of thromboprophylaxis in MAS (hernias, proctology, etc). As far as we know, there are only three non-randomised studies: the first involved a short series of 114 patients undergoing inguinal hernia repair [27] who were treated with calcium heparin at low doses, but with the aim of assessing the influence of the injection site on the appearance of complications at the level of the post-operative wound. The second one was a retrospective study [14] in 1854 patients operated for hernias who received prophylactic heparin, although the authors did not refer to the reason for its indication (risk stratification) or the methodology used (type, dose, initiation and duration). The last one was a non-randomised observational prospective study [28] in which Bemiparin (LMWH) was used prophylactically in 203 patients undergoing open or laparoscopic abdominal wall surgery (hernias and eviscerations) with moderate (81.1%) or high (26.1%) risk factors according to the THRIFT Consensus Group from 1992. However, the greatest problem with this study is that no systematic screening of deep vein thrombosis (DVT) was performed.

Despite the poor reliability of the few data available, there is concern about the need for thromboprophylaxis in this type of patient, as demonstrated by the existence of many questionnaires addressing the issue [17,24,29–31]. According to the opinions of the surgeons involved in them, who were from different European and North American countries, the issue should remain under debate since some studies involved stratified risks, while some did not; in some, thromboprophylaxis was implemented, while in others it was not. What is certain is that the numbers and complexity of MAS are increasing and hence it is not surprising that many such questionnaires conclude by requesting the creation of some kind of consensus as regards the actions to be taken.

Many scientific societies and panels of experts have proposed recommendations concerning the prevention of VTE in surgical patients. However, there are very few specific recommendations for MAS. This has led to uncertainty and variability in the guidelines for action. A consensus in this regard was reached in 2006 by the Spanish ASECMA group [5].

Our prospective study, mainly related to abdominal wall surgery, has allowed us to validate the above mentioned consensus concerning thromboprophylaxis with LMWH in MAS. Our observations support the hypothesis that one group of MAS patients was at low risk and did not require thromboprophylaxis with LMWH. This first group formed more than one third of the series (141/402). Since prophylaxis with LMWH is not free of risks in MAS, mainly in the form of haemorrhage (22,28,32), this group benefited additionally from the non-implementation of a systematic policy of prophylaxis in MAS.

Complementary to the stratification of VTE, we were surprised to find that nearly two-thirds of the patients were at moderate or high risk. In them, as in other studies (33), Bemiparin – a second generation LMWH – at doses of 2,500 and 3,500 IU/day, depending on the individual risk, proved to be effective in preventing VTE. Additionally, it proved to be effective when administered in the post-operative period, the risk of haemorrhage (including the injection site) being very low, as reported previously [34].

Logically, since there are few data available about the indication for LMWHs in MAS, there are even fewer data concerning the way such compounds are used. According to the review of Ahonen [16], the optimum time for initiating thromboprophylaxis in MAS is 6 h after surgery. Since there is no evidence to support single dose or 1–2 days of thromboprophylaxis, we chose the protocol indicated in most studies, which extends administration to 7–10 days or until the patient feels confident about walking normally [1,2)].

One of the major limitations of our study is the assessment of the results. As reported by Geerts et al [1], trials should measure efficacy and innocuousness together as the optimum result. Owing to the strong concordance between asymptomatic DVT and VTE, DVT must be investigated through the use of sensitive detection tests such as phlebography. However, although phlebography is sensitive for the detection of DVT, it is invasive, regardless of whether 20-40% of the venograms are considered non-diagnostic, and the clinical outcome of small thrombi seems uncertain. In contrast, apart from its low cost colour Echo-Doppler (ED) is a well known method for the diagnosis of DVT [35], is widely available, is non-invasive (non-iatrogenic) and is repeatable. However, the accuracy of ED is reduced in the case of the calf veins, is operator dependent, and the assessment of ED in clinical trials is difficult [36]. The sensitivity of ED in the follow-up of asymptomatic patients in the post-operative period has been questioned [37].

Aware that each method has its strengths and weaknesses, we thought it excessive to request a bilateral phlebography for the asymptomatic ambulatory patients. Accordingly, it is strange that many trials, mainly in laparoscopic surgery, have used ED [7–10,37,38]. With a serial bilateral ED (where necessary), results such as symptomatic VTE (or the combination of asymptomatic VTE and asymptomatic proximal DVT) can be objectified, together with the most important results on safety. In fact, the combination of venous compressibility and a study of spectral flow are the elements that provide the best sensitivity and specificity as regards the detection by ED of probable thrombotic problems in the venous system of limbs.

Normal venous flow is characterised by the absence of echoes or by a discrete intralumen echogenicity and a continuous flow inside the vein. The typical aspect of the spectral wave in the lower limbs is that of a spontaneous, phase-like anterograde flow, the fascicity being governed by the movements of inspiration-expiration under normal conditions. If cardiac alterations are present, the pressure in the right auricle will also lead to changes in the shape of the wave. It is also known that flow velocities in the arterial system are fairly constant in the different territories of the body, which is not the case of venous velocities, which are subject to many factors such as respiratory movements, the cardiac cycle, blood volume, valve competency, and even the body mass index, among others. In our series, although there was considerable variability in venous flow velocity, as mentioned previously, we performed a second assessment one week after the first one and after recommending continuation of the treatment with LMWH (in cases in which it was being administered) when we detected flows of les than 10–15 cm/s. All patients had improved their velocities by the second exploration.

In light of our results, it may be concluded that in MAS there are different groups at risk of VTE. The low risk patients only require the usual preventive measures (e.g., early and maintained walking) and do not need LMWH, thus being free of possible risks attributable to the drug. Nevertheless, there are larger groups with risk factors. To confirm whether these groups are at risk, might it be right to perform a randomised controlled study with a placebo in such individuals?. Clearly, with the results it would be possible to determine whether these groups, which we have called moderate and high risk (as a function of the stratification carried out), require LMWH at the above described doses over time. In view of the results on efficacy and safety, we would not feel confident about taking such a step, especially since we observed an important number of situations of venous stasis and hidden thrombophilia, both of which are able to further exacerbate risk. Another possibility would be to modify some aspect of the methodology used for the administration of LMWH. It would seem that initiation at 6 h after anaesthesia (especially in the case of neuroaxial anaesthesia) would be an ideal moment to start pharmacological thromboprophylaxis, since it does not modify efficacy and increases safety. However, in view of the ambulatory nature of this type of patient, it might be more interesting to reduce the administration of the drug to 1–2 days, which – without changing effectiveness – could improve the safety parameters and overall costs.

In summary, MAS is not free of VTE events. The risks of this kind of patient need to be stratified in order for the pertinent decisions to be taken. Patients considered to be at moderate/high risk of VTE benefit from post-operative administration of Bemiparin, with a low risk of -mostly minor- complications. This prophylactic practice is effective and safe and is accepted by most patients who demand of MAS the maximum quality in medical attention.

Addendum: the role of each author

Francisco S. Lozano: conception and design of the study, data acquisition, analysis and interpretation of the data, manuscript drafting and administrative support.

José Sanchez-Fernandez: data acquisition and interpretation (study surgeon), statistical analysis, and critical review of the manuscript.

José A. Santos and Jesús García-Alovio: data acquisition and interpretation (study echographists), critical review of the manuscript.

Rafael Mateos: data acquisition and interpretation (study surgeon) and critical review of the manuscript.

José R. González-Porras and Ignacio Alberca: data acquisition and interpretation (study of thrombophilia), critical review of the manuscript.

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Pain and Other Adverse Symptoms Identified by Follow-up Telephone Call after Ambulatory Inguinal Hernia Repair

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Abstract

Aim: This retrospective study reviewed information that was collected as part of the post-operative follow-up telephone call, to identify if pain or other adverse symptoms were acknowledged as a problem by patients following inguinal hernia surgery.

Method: Charts of 98 male patients who underwent inguinal hernia surgery between March 2006 and March 2007 were examined. A standardized check list was used to gather information regarding pain and adverse effects from patients on post-operative day [1]. The information gathered using this standardized check list was examined.

Results: Pain was the most commonly reported adverse symptom with 81% of patients indicating they experienced pain. Eighty-six patients (87.7%) used their prescribed analgesics to manage their pain. The most commonly prescribed analgesic was 325 mg acetaminophen with 30 mg codeine.

Key words: inguinal hernia, ambulatory surgery, pain, nursing

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Introduction

Surgical procedures that previously required hospitalization for one to two days are more frequently performed on an ambulatory or outpatient basis. This shift to ambulatory surgery is related to advances in anesthetic and surgical techniques, as well as fiscal restraints. In Canada, the number of patients having ambulatory surgical procedures has increased dramatically over the past two decades. The Canadian Institute of Health Information (CIHI) reports that the number of patients having these procedures has increased by 31% since 1996 [1]. However, 60% to 71% of patients who undergo ambulatory surgery experience unrelieved moderate to severe pain immediately post-operatively [2] and 34% to 55% patients continue to have pain seven days after their surgery [3, 4].

Inguinal hernia repair (IHR) is the third most common surgery performed in Canada and is usually performed as an ambulatory procedure [5]. This surgery has been identified as one of the most painful ambulatory surgery procedures, with 54% of patients experiencing moderate to severe pain in the first 72 hours [2, 6, 7, 8]. Despite experiencing continued pain, patients do not always take the prescribed analgesics. Analgesics are helpful in managing post-operative pain but may have adverse effects, including nausea, vomiting or constipation, which are often not managed post discharge. Almost half of all patients who undergo ambulatory surgery experience such adverse effects, with 45% experiencing constipation and 46% experiencing nausea and/or vomiting in the first 48 hours after surgery [9]. Patients often report receiving little or no instruction on how to manage these adverse effects, particularly after discharge from hospital [2, 4]. In addition, patients may be reluctant to ask questions about pain and they often have many misconceptions regarding postoperative pain, including concerns about addiction to analgesics, the belief that moderate to severe pain is to be expected and contributes to healing and therefore is to be tolerated following surgery [2, 3, 4,7, 9]. Patients are expected to manage this pain and adverse effects of analgesics themselves at home.

This study planned to review information that had been collected over a 12 month period as part of the post-operative follow-up telephone call after ambulatory surgery at a large University affiliated teaching hospital in Ontario, Canada. The aim of the study was to identify if pain or other adverse symptoms were acknowledged as a problem by adult patients as a result of ambulatory inguinal hernia repair.

Method

Following institutional research ethics board approval patient's charts were retrospectively reviewed. Inclusion criteria included: male patients age 18 or older that were discharged home on the same day as their inguinal hernia surgery. On the first post-operative day, patients received a telephone call from a nurse from the same day surgery unit to determine if the patient had any adverse effects or required any additional information after surgery. A standardized check list was used to gather information from patients and included questions regarding the presence of: pain, sore throat, fever, weakness, headache, nausea/vomiting, drainage, sore muscles, swelling, redness or bleeding.

The standardized check list also included questions regarding patient's activity, analgesic use, unplanned use of health care

resources (telephone calls to primary care physician, surgeon or visit to the hospital), and the clarity of discharge instructions and the need for additional information. The information gathered using this standardized checklist was examined. Data were analyzed using descriptive statistics and reported as means.

Results

The charts of 98 consecutive male patients who underwent inguinal hernia surgery between March 2006 and March 2007 were examined electronically. The mean age of patients was 55.6 years. The most common type of inguinal hernia surgery was right inguinal hernia repair with mesh (n = 27).

Table 1

Type of Inguinal Hernia Surgery	Number of Patients
right inguinal hernia repair with mesh	27
right inguinal hernia repair	15
right laparoscopic inguinal hernia repair	9
right laparoscopic inguinal hernia repair with mesh	5
left inguinal hernia repair	12
left inguinal hernia repair with mesh	13
left laparoscopic inguinal hernia repair	5
left laparoscopic inguinal hernia repair with mesh	8
bilateral hernia repair	4

When asked about specific adverse outcomes during the post-operative telephone call, patients most frequently reported the presence of pain, bleeding from the surgical site (that resolved within 24 hours), difficulty voiding (that resolved within 24 hours), sore throat, and nausea and vomiting. Pain was the most commonly reported adverse symptom after inguinal hernia surgery, with 79 patients (81%) indicating they experienced pain. Eighty-six patients (88%) used their prescribed analgesics to manage their pain. The most commonly prescribed analgesic was 325 mg acetaminophen with 30 mg codeine (Tylenol #3). Two patients called their surgeon for additional information/advice post-operatively. None of the patients presented to the hospital in the first 24 hours following surgery due to adverse symptoms. All patients were satisfied with their discharge instructions and did not ask for additional information during the telephone call.

Table 2

Reported Adverse Symptom	# Patients Reporting Symptom (%)
Pain	79 (81)
Bleeding	18 (18.4)
Difficulty voiding	9 (9)
Sore throat	7 (7.1)
Nausea and vomiting	6 (5.8)
Drainage	1 (1)
Fever	1 (1)

Conclusion

This chart review found that when nurses asked about the presence of specific outcomes during post-operative telephone call, patients reported several adverse events. The most frequently reported adverse event was pain, followed by bleeding from the surgical site (that resolved within 24 hours), difficulty voiding (that resolved within 24 hours), sore throat, and nausea and vomiting. The majority of patients used the prescribed analgesics to manage their post-operative pain. Implications for nursing practice includes: providing pre-operative education regarding the potential presence of these symptoms post-operatively and symptom management techniques, post-operatively exploring how patients are managing adverse symptoms and providing patients with alternative management techniques if necessary.

Future research directions include determining the presence and the severity of adverse symptoms experienced by patients, as well as preventing or pre-emptively managing adverse symptoms whenever possible. The high incidence of postoperative pain for patients having elective ambulatory inguinal hernia repair suggests that the standard therapy with acetaminophen with codeine should be reconsidered.

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Progress of Day Surgery in India

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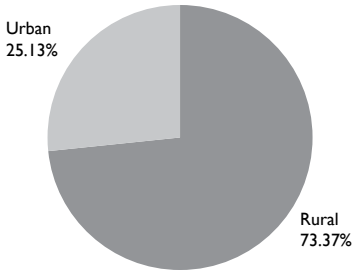
Introduction

Ambulatory surgery in India is still a new concept of modern surgical care. Organized delivery of standardized surgical care, in the form of Day-case, is now an accepted norm in the specialties of Ophthalmology and ENT, but in others, still confined to minor / OPD procedures.

In India, the current trend is to establish Super-Specialty Tertiary health care facilities, which provide Coronary by-pass and Hip replacement. These, of course, are definitely required for advancement of medical care. The Health Ministry is working towards encouraging medical tourism, facilitating visas for a smooth flow of patients. Last year, approximately 1.5 million patients were seen for treatment in these tertiary hospitals. But, Day Surgery is not really a priority for them, as yet.

Organization of health care

A population of 1,073,000,000 (over a billion and growing), out of which 73.87% live in villages and smaller towns, and only 26.13% reside in larger towns and metro cities. Therefore, health care in India becomes a formidable task.[1]



Yet, we have one of the most unique health care systems. The two basic systems are public and private health care providers. Public hospitals are funded by the state and central government. These are utilized by almost 60% of population. Apart from certain larger hospitals, where the funding is reasonably good, most lack in facilities due to shortage of funds. Out of the total expenditure on healthcare in the country, this amounts to only 17 %.[2] On the other hand, private sector health care, where facilities are comparable to most developed countries, cater to just 40% of the country's population, yet take the burden of 83% of healthcare expenditure. Therefore, the per capita expenditure on private health care is 4.2% of the GDP and public health is about 0.9% GDP (totaling to 5.1% of the GDP). This makes it one of most privatized health care systems in the world.[3]

Due to lack of facilities and infrastructure as well as shortage of doctors and nursing staff in the public sector, there has always been a growing trend to seek treatment in private hospitals and clinics. Here, the patient pays for his treatment, sometimes needing to borrow or sell assets to fund the treatment. Apparently, every year, about 16% of the population is pushed below the poverty line due to health expenses. The private sector has facilities and trained staff comparable to any developed country, but available at a premium.

Health insurance

At a National level, just 2% of the popoulation is covered under Medical insurance. Mumbai, the commercial capital of India, has a population of approx. 20 million but only 20% of its citizens are covered by health insurance.

A mandatory insurance requirement of 24 hours admission or overnight stay, made it easier to pay claims but has restricted the concept of Day Surgery. However, after extensive correspondence over a period of four years, working with the Insurance Regulatory & Development Authority and service providers, there is now a change in the policy. This new policy has included a clause stating 'procedures performed by the advancement of technique, or utilization of specialized equipment, e.g. LASER, etc., do not require overnight stay in the hospital' and '. . . Surgeries performed at specialized centre . . . ', represent the first step in a logical change that is required for the advancement of Day surgery. Hopefully, more and more cases will be added to the One Day Surgery list, creating an acceptable 'basket' as followed elsewhere in the world.

Problems faced

Lack of awareness is the main difficulty we face. There is a tremendous lack of awareness among the patients as well as doctors.

The suggestion of surgery creates a fear psychosis in most patients. On one hand, they do not want to go home for the fear that they might face some complications which may not be managed once they

are out of the hospital, so they wish to continue to stay in the hospital 'till the stitches are out'. On the other hand, 'discharge on the same day', reduces the magnitude of surgery in patient's minds, convincing the patient to undergo the procedure.

As yet, there is no definite government policy or support for One Day Surgeries. Nationally, the Bed:Patient ratio is 1:1,123, making it impossible to procure a bed in case of emergencies. There is an estimated shortage of 42,000 beds in government hospitals, which cater to 60% population.[4] Most hospitals perform Day Surgery as part of the regular surgical list. According to latest government estimates, the doctor: patient ratio is 1:1,800 and hospital bed: patient ratio is 1:1,462.

The flow of patients is from villages to nearest city, to District hospitals, to Hospitals in larger state capitals & ultimately, to hospitals in metropolitan cities. This drive starts with a lack of basic infrastructure in villages, and therefore, a belief that care is better in cities. This trend or shift is seen more in favor of private facilities, which come at a premium. The Public hospitals are overwhelmed by the inflow and unable to handle the overcrowding. The government in turn is doing whatever it can, but still a tremendous amount needs to be done.

Solutions

The Indian Association of Day Surgery was founded in the year 2003, with 262 Life members so far. It is a national organization, with members from 18 states and different surgical specialties, including anesthesiologists and dental surgeons. We had stickers made for doctors' cars, proclaiming them as members of the Association!

To date, four National Conferences have been organized. The first conference was in 2005 at a Naval Hospital, attended by Defense service and civilian doctors. The scientific session lasted for 10 hours straight, with 29 guest lectures covering all the aspects of One Day Surgery. To commemorate the occasion, a First-Day postal cover was released.

A handbook on Protocols of a Day Care Surgery was released during the first national conference. It gives a complete and concise insight on patient selection, patient preparation, instructions to patients, list of surgery, types of anesthesia, design of a centre, and its day to day running. This book also includes many useful forms, such as like admission and consent forms, including advantages and disadvantages, as well as complications and management of complications.[5]

Day Surgery Journal of India was launched during the proceedings. It is an annual publication, with a collection of articles from all over the world. It is provided free of charge to all the Association's members as well as sent to every Medical College library in the country. Articles can also be read on-line on the Association's website.[6]

During the subsequent three conferences, issues on protocols, insurance, medico legal and progress were discussed. The conferences were held in and around the city of Mumbai at various hospitals.

The 4th National Conference saw the inception of an Oration. It was given by a representative of the Medical Council of India and a Member of Senate of the State Medical University, who was positive towards the inclusion of the concept of Day Surgery in the undergraduate and postgraduate medical education in India.

Increasing awareness is another organization goal. The initial reaction of patients and doctor colleagues is of surprise at no-overnight stay. Apart from holding seminars, scientific meetings, workshops and publications, a major advertising campaign is required (within the permissible medical ethics).

One Day Surgery Centre

Establishment of a multispecialty, free standing One Day Surgery Centre in every major city in India, seems to be the ideal way to show the effectiveness of this concept. The first of its kind has been started in the metropolitan city of Mumbai, which is the most popular destination for Medical treatment in India, as well as for medical tourism. Another centre is situated in Nagpur, a large central Indian town.[7] The uniqueness of these centers is that they are Certified by ISO 9001-2000 & 2008, the quality manuals and operational procedures of which have incorporated protocols for a Day Surgery Centre. These include and stringently follow pre and post-operative instructions, discharge criteria and other checks.

'One-Day Surgery Times' newsletter is released every month and circulated amongst general practitioners and family physicians. It carries articles, news and information pertaining to Ambulatory Surgery.[8]

Challenges face these centres. Nursing staff need more training and orientation towards Day Surgery. Patient education is of prime importance. Who can convince the patient more than the operating surgeon? It means more time spent with the patient, but a confident patient means a successful recovery.

In summary

India is a rapidly developing and growing nation. Since a large part of its population is low to middle income, it is but logical to assume the tremendous benefits the concept of Day surgery will have. A multi pronged approach and continuous dialogue with all concerned, however slow, will be the essence in working towards our goal of establishing One Day Surgery Centers in each city. It is only a matter of time. Like anywhere in the world, Day surgery will be the Future of Modern Surgery in India as well.

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Outpatient hemi-thyroidectomy: is it safe?

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Abstract

Aim: To compare the safety of hemi-thyroidectomy following the procedure between ambulatory and inpatient surgical regimens.

Methods: 100 patients consecutively submitted to hemi-thyroidectomy (between 2005–08) were selected: Group 1–50 inpatients; Group 2–50 outpatients with discharge on the same day. A retrospective analysis was performed. Clinical features were not factors in the selection of the regimen. Information about gender, age, ASA score, and clinical features, drains, hospital length of stay and post-operative complications was recorded. An additional questionnaire by telephone was performed after the procedure.

Results: The median of age was significantly older in Group 1. No significant differences between groups were found in gender, ASA score or educational level. Drains were kept significantly longer in the inpatient group. The number of major complications was low, consistent with the accepted norms and not statisticallly different between groups. No life-threatening complications were reported.

Conclusion: An outpatient procedure has well-established advantages. The results suggest that safety is comparable in both regimens. With an increase in surgeons' experience, and an adequate selection and education of the patients, the one day surgery regimen can offer a higher volume of surgery associated with cost reduction.

Key words: Hemi-thyroidectomy, Day case, ambulatory surgery

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Introduction

The current practice for post-operative care of hemi-thyroidectomy patients uses mostly the inpatient setting [1–8], with multiple day hospitalisation. However, while the thyroid is a relatively superficial organ, and mortality rates are extremely low, ambulatory approach to this type of surgery can be explored.

With better healthcare provision in all sectors and with the developments in post-surgical patient care and monitoring, an increasing number of surgical operations can be carried out safely in a day surgery setting [9]. These have resulted in improved patient satisfaction and cost savings [5, 6, 8, 10]. Therefore, accompanying the current trend, there has been a move towards shorter stay for thyroid surgery [1, 5–7, 11].

Since 1991 several reports documented experience with the same day discharge for a range of thyroid surgeries from simple lobectomy to total thyroidectomy [11, 12]. Nonetheless ambulatory thyroidectomy remains a highly controversial approach [4, 8, 11, 12].

In our study concerning thyroid surgery, hemi-thyroidectomy was chosen because of the higher homogeneity of the pathology and its conventionally lower rate of complications [7, 12–14]. This study aimed to validate our current practice, hoping to contribute to the expansion of this programme in our day surgery unit (DSU), increasing patients' accessibility and reducing the waiting surgical lists in this field.

Methods

This is a single centre retrospective study, comparing patients consecutively scheduled for hemi-thyroidectomy as an elective primary procedure between 2005– 08. Two groups of patients were compared: Group 1–50 inpatient regimen and Group 2–50 outpatient regimen (with discharge on the same day).

Clinical features of the patients and pathology were not factors in the selection of the regimen. Exclusion criteria for outpatient surgery were: rejection of ambulatory regimen by the patient, lack of motivation for an outpatient procedure, cognitive disability or low educational level that could not permit an early recognition of the alert signs of a major complication, home distance from hospital over 20km, and lack of adequate home facilities. Patients having the previous criteria and organizational reasons were assigned to an inpatient procedure.

Ambulatory patients were monitored in the Day Surgery Unit for at least six hours after surgery and were discharged after having been evaluated by the surgeon. Specific instructions were given to all patients to return to the hospital in the event of neck swelling, excessive drain bottle accumulation, respiratory distress, or signs of infection or hypocalcaemia. Patients were scheduled to return to the clinic for routine assessment in the following day. Cervical drains if present were removed when the drainage was minimal.

All major complications were recorded: wound infection, cervical haematoma compromising airway or causing need of re-intervention, need of re-intervention for any other aetiology, significant haemorrhage and symptomatic hypocalcaemia. Information about gender, age, ASA score, and clinical features, minor complications, drains was collected. An additional questionnaire by telephone was performed after the procedure.

Data was statistically analysed by Mann-Whitney and $\chi 2$ tests (Table 1) and age-adjusted odds ratio test calculated by logistic regression. Continuous variables were expressed as mean $\pm$ SD for symmetric variables and median (25^{th}–75^{th} percentiles) for asymmetric variables. The categorical variables were expressed as relative frequencies. Differences were considered statistically significant when $p < 0.05$.

Results

The median of age was significantly higher in Group 1, and no other demographic differences were observed (Table 1). No significant differences between groups were found in gender, ASA score or educational level. The majority of the patients in both groups had a cervical drain. The length of stay median in the inpatient setting was 5,9 days. All patients in the Group 2 were discharged home in the same day of surgery. The number of major complications was not different between groups (Table 2). Surgical re-intervention occurred in 2 outpatients and in 1 inpatient. Significant haematoma occurred once in both group after discharge (an outpatient reported mild dyspnoea, but no significant respiratory distress occurred). The wound infection rate was not significantly different between groups. In 2 inpatients hoarseness was present at least 2 months after de procedure. No life-threatening complications were reported.

Table 1 Demographic data.

	Inpatients	Outpatients	P
Age*	61 (47–71)	47 (39–58)	<0,01
Females†	36 (72)	40 (80)	0.35
≤9 years completed at school †	38 (76)	34 (68)	0.37
ASA score*	2 (2–2)	2 (2–2)	0.25

* Median (interquartile range), Mann-Whitney test † n (%), $\chi 2$ test

Discussion

There are some studies on safety of ambulatory thyroid surgery [1–3, 5, 10, 15]. The growing number of short stay thyroid surgery is probably due to low rates of significant complications and moderate levels of pain and discomfort, allowing patients to go home once they recovered from general anaesthesia. Additionally, ambulatory thyroid surgery has been proven to be less expensive and cost-effective [1–3, 5, 10, 11, 13, 15].

Hemi-thyroidectomy generally has low complication rates, but if they occur, they may have serious consequences. Neck hematoma and bilateral vocal cord palsy can lead to respiratory compromise. Hypocalcaemia is not likely to occur in hemi-thyroidectomy, but if occurs, it may result in neurological sequelae. [4, 12, 14]

Since most patients with no pre-existing comorbidities can usually be discharged on the first postoperative day, the main reason for performing hemi-thyroidectomy in the inpatient regimen should be to monitor patients for the development of these rare but potentially life-threatening complications [12]. The exclusion criteria for the outpatient hemi-thyroidectomy, besides the logistic reasons, concern safety. Patients in the ambulatory group were younger and capable of understanding the specific risks of the post-operative period and act correctly if any complication occurred. In this study, the observed rate of complications for both groups corresponded to the accepted norms [5, 16, 17]. As expected, there were no cases of symptomatic hypocalcaemia, and, although advocated by some authors [4, 5, 8, 12] calcium supplements were not routinely administered.

Table 2 Outcomes..

		Inpatients	Outpatients	p
Complications (total)†		10 (20)	8 (16)	0.60
Life-threatening complication		0	0	-
Major complications†		4 (8)	4 (8)	1
	Haematoma associated to mild dispnea	1 (2)	0	
	Haematoma (need to reintervene)	0	1 (2%)	
	Re-intervention (partially retained drain)	0	1	
	Wound infection	1 (2%)	2 (4%)	
	Hoarseness (present at least 2 months after the procedure)	2 (4%)	0	
Other relevant complications reported n (%)		0	2 (4%)	
	Haemorrage (drain kept longer)			
Patients with drains†§		43 (86)	48 (96)	0.08
Nr. of days with drain*		3 (2-4)	2 (1-3)	<0.01
Period of hospital stay (days)*		5.9 (4.0 -6.3)	1	<0.001
Unplanned visit to hospital†		4 (8)	8 (16)	0.22

*Median (interquartile range), Mann-Whitney test † n (%), $\chi 2$ test

Major complication considered: Wound infection, cervical haematoma compromising airway or causing need of re-intervention, need of re-intervention by any other aetiology, significant haemorrhage and symptomatic hypocalcaemia.

§ Data referred to 91 patients

The majority of postoperative haematomas occurs within the first few hours after surgery, or when it occurs later, warning signs can be frequently identified in early post-operative period [5, 10, 11, 12, 18, 19]. However, haematomas can present as late as five days after surgery [12, 18]. Literature indicates that airway obstruction may occur up to 16 hours postoperatively [17]. We found no significant difference in the rate of complications between the ambulatory and inpatient groups. Two of our patients developed haematoma (one in each group). In fact in both cases in our study (one in each group) haematomas occurred late, and no warning signs where identified (both required non-emergent cervical exploration). No significant respiratory distress or acute airway obstruction has occurred, although mild dyspnoea/cervical discomfort was observed in one patient.

For ambulatory hemi-thyroidectomy to become widely accepted the rate of wound haematoma must be low, not greater than one to two percent [6, 8, 18]. Both patients and staff must be aware that serious and life-threatening postoperative complications can be identified and managed safely. The outpatient model must involve two phases of care, the first takes place in a specially prepared ward and the second involves continued monitoring of the patients after discharge from hospital [12, 13].

Careful preoperative selection and a clearly-defined management protocol are necessary to make ambulatory thyroid surgery a safe and accepted alternative to inpatient care. In our retrospective study, primary hemi-thyroidectomy was carried out safely in the ambulatory setting for a selected group of patients. The incidence of postoperative complications was low and comparable in the ambulatory group and inpatient groups. The management of patients undergoing ambulatory hemi-thyroidectomy should therefore include careful preoperative selection, appropriate patient and caregiver education, optimal immediate postoperative monitoring in an adequately set-up ambulatory care facility, and adequate protocols for management of patients with postoperative difficulties.

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Perioperative Management of Super Wet Liposuction: A Case Report

Didier Sciard MD§ and David G Leiman MD‡

Abstract

We describe a patient who presented in acute respiratory distress following liposuction under general anesthesia. Clinical manifestations and radiologic findings were consistent with fluid overload and acute pulmonary edema. Fortunately the patient recovered well from this complication. Perioperative fluid management during liposuction is discussed.preconditions for improving whole DS systems and their components, such as a network of DS clinics.

Key words: liposuction, super-wet technique, general anesthesia, pulmonary edema.

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Super wet and tumescent liposuction techniques can lead to large fluid shifts and over hydration of patients. We present a patient who exhibited fluid overload and pulmonary edema following super wet liposuction.

Case description

A 25-yr old, 72 kg, 162cm ASA 1 women was admitted to a surgery center for a suction assisted lipectomy of the hips, thighs, buttocks and abdomen. Her past medical history included a previous rhinoplasty and mini liposuction with no complications. Current medications included iron, levothyroxine, doxycycline, and birth control pills. Levothyroxine was given in absence of any known dysthyroid syndrome.

Her physical examination was normal, and her preoperative vital signs were: BP 110/70, P 76, RR 16, T 97.6, and room air SpO_2 100%. Her starting hemoglobin was 14.1g/dl. On the day of surgery the patient received cefazolin 1g and midazolam 2 mg IV via a 20 gauge IV placed in the dorsum of the right hand prior to entering the operating room. In the operating room, the patient was monitored with an electrocardiogram, noninvasive blood pressure, and pulse oximeter. General anesthesia was induced with propofol 140 mg and fentanyl 50 mcg and muscle relaxation achieved with vecuronium 7 mg. She was intubated with a 7.0 ET tube and anesthesia was maintained with 50% inspired oxygen in air and 1.5–2% sevoflurane. After induction, another bolus of 50 mcg of fentanyl and 50 mg of meperidine was administered as well as 8 mg of dexamethasone and 6.25 mg of promethazine. Another dose of vecuronium 3 mg was administered 90 min after the first dose for a total of 10 mg.

During the first hour of surgery the patient was in the dorsal decubitus position and then repositioned in the prone position for the remainder of the surgery. Tumescent liposuction was performed and the patient received a total subcutaneous infiltration of 4000 ml of normal saline solution that contained 90 ml of 0.5% lidocaine with 1:1,000,000 epinephrine. The operation was uneventful and lasted 3 hours and 50 min. The patient remained stable with a typical blood pressure of 120/65, heart rate 65-85 beats per minute, and SpO_2 99%. At the end of surgery, muscle relaxation was reversed with neostigmine 2 mg and glycopyrrolate 0.4 mg. Prior to emergence, ondansetron 4 mg was administered. Intravenous fluid administration consisted of 4000 ml of Ringer's lactate and 1000 ml of hetastarch. The total aspirate was 5200 ml, with an estimated blood loss of 600 ml, and urine output of 450 ml.

In the post anesthesia care unit (PACU) vital signs were as follows: BP 130/80, P 104, RR 16, T 94.4 and SpO_2 97% on 6l/min O_2 via face mask. The patient complained of pain and received intravenous hydromorphone 0.1 mg 25 min after arrival and was encouraged by the nurse to take slow deep breaths because her SpO_2 had dropped to 88%. After one hour in PACU, the patient became very anxious and complained of increased difficulty in breathing. At this time her respiratory rate was 24, SpO_2 77%-88% on 6L/minO_2 via facemask, BP 117/65 and P 119. An anesthesiologist was consulted and the patient was placed on a 100% non-rebreather mask. Lung auscultation demonstrated bilateral and diffuse crackles. The patient was then given furosemide 20 mg and 2 doses of morphine 2 mg.

Approximately 30 minutes later, the patient was feeling better, O_2 saturation was 93- 96% on 100% non-rebreather mask and good urine output. A chest radiograph demonstrated markedly diffuse bilateral pulmonary infiltrates. An arterial blood gas was obtained, with pCO_2 30.8 mmHg and pO_2 73.1. During the next 2 hours, the patient's condition improved. She drank 200 ml of water/apple juice. Her total urine output was 2575 ml. At this time, she was admitted to the hospital for further evaluation and treatment. The patients' vital signs were as follows; BP 132/79, P 133, RR 30, T98.2 and SpO_2 96%, on 2 L/min O_2 via nasal canula.

On admission another dose of furosemide 20 mg was given, as well as a total of 14 mg of morphine over the next 24 hours. A CT pulmonary angiogram was performed which demonstrated diffuse patchy parenteral consolidation throughout both lungs without any evidence for pulmonary emboli. The patient's condition gradually improved over the next 24 hours and oxygen administration was discontinued. Oxygen saturation on room air remained stable (96–98%), pain was controlled, and the patient was discharged home. Patient's 24-hour intake and output showed a positive balance of 750 ml with a total urine output of 6800 ml (table).

Table

Time	0700–1400	1500–2200	2300–0600	24 hour total
In/Out (ml)	5000/1050	360/1750	720/4000	6050/ 6800

Discussion

Tumescent and super wet liposuction techniques have become common practice today as a means of providing analgesia and to decrease blood loss associated with liposuction [1–2]. Tumescent and super wet techniques rely upon large volumes of irrigation (1:3 fat aspirate to irrigation for tumescent and 1:1 for super wet) with the addition of lidocaine and epinephrine. The dose of lidocaine can be well beyond the standard maximum dose recommendations (4 mg/kg or 7 mg/kg with epinephrine), up to 55 mg/kg. With a dramatic rise in cosmetic surgery, the anesthesiologist must be aware of the adverse outcomes associated with this type of procedure [3–5]. The combination of the anesthetic technique and the procedure predispose the patient to several potentially fatal adverse outcomes. The adverse outcomes can be from lidocaine toxicity, fluid overload, and fat or pulmonary embolism [6–8] In this case, we encountered a patient with fluid overload and pulmonary edema.

Proper fluid management and awareness of the fluid shifts taking place with these procedures is extremely important. Literature regarding fluid management for these procedures is sparse. Trott et al recently presented a formula for resuscitation and recommended to replace the fluid deficit and the insensible losses for the procedure with 0.25 ml of crystalloid for every 1 ml of tissue removed beyond 4000 ml. They were able to demonstrate that an intraoperative fluid ratio (intravenous fluid plus subcutaneous infiltration divided by aspiration volume) of 2.1 for volume of aspirate below 4000 ml and 1.4 for large volume liposuction (> 4000 ml) was safe and that the urine outputs during the procedure reflect a mild over-resuscitation with this formula [9]. A repeat study performed by Rohrich et al keep used the same formula and compared it to a formula where all the fluid replacement variables were the same except 0.25 ml of crystalloid was administered for every 1ml of tissue removed beyond 5000 ml. Their intraoperative fluid ratios were 1.8 and 1.2 respectively for volumes of aspirate below and above 5000 ml and urine output between 1.5 and 2.5 ml/kg. These relatively high urine outputs demonstrated that the intraoperative fluid ratio could be further improved perhaps by eliminating fluid replacement [10].

In this report the anesthesiologist replaced the aspirate volume for volume and intraoperative fluid ratio was 1.9. Because only a small portion of the volume of crystalloid solution given intraoperatively remains intravascular, patients can have significant weight gain and fluid retention secondary to third-space loss. The sparse reporting of adverse outcomes makes it difficult to assess the level of morbidity and mortality associated with these techniques: however, when performed under general anesthesia, these procedures may be at higher risk for fluid overload compared to the same procedure performed under local anesthesia [11–12]. Thus anesthesiologists should be aware that large volume IV fluid replacement could be deleterious in these procedures as patients also receive large volumes of absorbable irrigation [13-15]. Evidence of fluid overload should be treated accordingly.

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