Rom J Leg Med [29] 60-64 [2021]
DOI: 10.4323/rjlm.2021.60

SAFE SURGERY IN DAY CARE CENTERS: FOCUS ON PREVENTING MEDICAL LEGAL ISSUES

Dragoș Șerban[1,2], Cristian Mihai Brănescu[2], Gabriel Cătălin Smarandache[1,2], Corneliu Tudor[2], Ciprian Tănăsescu[3], Mihai Silviu Tudosie[1], Daniela Stana[4], Daniel Ovidiu Costea[5,6], Ana Maria Dascălu[1,4,*], Radu Iulian Spătaru[1,7]

[1]"Carol Davila" University of Medicine and Pharmacy Faculty of Medicine, [2]Emergency University Hospital, IV[th] Surgery Dept., Bucharest, [3]"Lucian Blaga" University, Faculty of Medicine, Sibiu, [4]Emergency University Hospital, Ophthalmology Dept., [5]Ovidius University Constanta, Faculty of Medicine, [6]Emergency County Hospital Constanta, General Surgery Dept., [7]"Marie Curie" Emegency Children Hospital, Surgery Dept., Bucharest, Romania

Abstract: Under the pressure of economic efficiency of medical care, day care surgery is a growing concept which should be considered more frequent in the clinical practice, in all surgical specialties. On the other hand, early discharge after surgery comes with its own challenges, which can result in medico-legal issues if the outcome is not totally favorable for the patient. The paper aims to review the previous published articles on the specific challenges related to safe surgery in the day-care environment. A search was performed on PubMed/Medline, Springer Nature and Google Scholar for all papers published between 2000 and 2020, by the terms: "day care surgery" and "safe surgery" and/or "medico-legal issues". The concept of "day surgery" or "outpatient surgery" has developed unevenly depending on the area and surgical specialties. Informing patients is particularly important, as they will become an active partner in the patient-physician relationship in preoperative training and postoperative care. A special attention must be paid to the proper selection of patients who can benefit from day-care surgery, in this sense a very important role is played by the decision of the anesthetist. When deciding whether a patient is acceptable for day surgery, multiple factors should be taken into account, to minimize the risk of medico-legal issues. While obviously not all the procedures could be performed on daily basis, there is clinical evidence that day surgery is safe and effective in elective cases, with an anticipated simple outcome, and in well selected patients. A complete preoperatory evaluation, as well as detailed information previous obtaining informed consent are extremely important to increase the safety and minimize the risk of adverse events in outpatient surgery.

Keywords: safety, day care surgery, risks, medico-legal issues, patients' selection.

INTRODUCTION

The spectacular development of diagnostic techniques and minimally invasive treatment in all surgical specialties, as well as the optimization of anesthesia conditions have led to the implementation of a new concept in surgical practice, namely day-care surgery. In recent years, it has become not only an option, but also a desideratum for elective surgery, experiencing a great development in the last 25 years, in all surgical specialties, from small branches, such as ophthalmology and ENT to abdominal and gynecological surgery.

The paradigm has changed radically since the 1948 BMJ editorial [1], which considers the benefits of early rising after major surgery questionable and considers that if a surgeon discharges a patient in the first 14 days after surgery, he is responsible for any complications might appear. Minimally invasive techniques allow rapid recovery, reduction of postoperative pain and postoperative complications and create favorable conditions for rapid postoperative integration into the social environment. On the other hand, early discharge after surgery comes with its own challenges, which can result in medico-legal issues if the outcome is not totally favorable for the patient [2,3].

METHODS

The paper aims to review the previous published articles on the specific challenges related to

*Correspondence to: Ana Maria Dascalu, MD, Assist. Prof., "Carol Davila" University of Medicine and Pharmacy Faculty of Medicine, Splaiul Independentei, no. 169, 050098, Bucharest, Romania, E-mail: ana.dascalu@umfcd.ro

safe surgery in the day-care environment, which can possibly result in medico-legal issues. A search was performed on PubMed/Medline, Springer Nature and Google Scholar for all papers published between 2000 and 2020, by the terms: "day care surgery" and "safe surgery" and/or "medico-legal issues". After duplication removal, articles and book chapters available in full text in English language were analyzed.

RESULTS AND DISCUSSION

The concept of "day surgery" or "outpatient surgery" has developed unevenly depending on the area and surgical specialties. Cataract surgery, with the widespread introduction of phacoemulsification techniques and foldable intraocular lenses, has become, globally, the most practiced global intervention in day hospitalization. Up to 96% of cataract cases are resolved on an outpatient basis in the USA [4,5]. In our country, the incidence of phacoemulsification in day hospitalization increased from 13.87% in 2014 to 35.62% in 2018, and this upward trend continues today[6]. Day Care surgery, especially developed in the USA, UK and Scandinavian countries, is still in its infancy in our country. Out of the 139 procedures from all surgical specialties contracted for day hospitalization (hospitalization under 12 hours) within the basic package with the national health insurance house, the highest weight has varicose vein surgery (39.48%), surgery cataracts (35.62%), corrective surgery for carpal syndrome (24.51%) and surgical treatment of hemorrhoids (16.23%), while more extensive interventions that require general anesthesia, such as laparoscopic cholecystectomy or treatment of inguinal hernia laparoscopically are performed less than 5% in day hospitalization [6]. This uneven development is related to health policies, the level of development of private clinics and the level of information and acceptance of this type of medical care by patients [4,7,8].

The advantages of day-care surgery

The concept of Day Care surgery is attractive for patients, because it offers the chance of an early return to the family environment after surgery, but also because it removes concerns related to hotel services, the frequent cause of dissatisfaction related to the medical-surgical act. Another advantage is that it reduces the risk of hospital acquired infections (HAIs), given the shortened time spent in the hospital [9-13].

For the service provider, day-care surgery means a more efficient use of resources, better planning of surgical interventions, previous interventions. In day hospitalization centers, the scheduling of interventions is possible with greater accuracy, the procedures performed being generally with less complexity. This hospitalization regime allows the reduction of personnel expenses and needs (night shifts, weekend shifts), given that qualified human resources are deficient in Western European countries and the United States [9].

For the health insurance system, the development of this sector means reducing costs, with the possibility of providing a higher number of quality medical services to patients, and, consequently, shortening waiting lists [4,8-12].

However, there is reluctance on the part of both doctors and in the absence of longer supervision, any unidentified complication in time can generate medico-legal claims. An important issue is the proper selection of patients suitable for day surgery.

Safety in day surgery

With the improvement of anesthesia and analgesia, as well as minimally invasive techniques in all surgical specialties, a wide range of interventions have been proposed to be performed on an outpatient or day surgery basis. Procedures fit for Day Care Surgery are considered those that meet the following criteria [9.15-17]:

- No special postoperative care;
- No expected intra or post operatory complications
- Minimal blood loss;
- Duration <1 hour, with minimal tissue trauma;
- Performed by minimal invasive approach.

Comparative studies in large groups of patients have shown that there are no significant differences in the rate of postoperative complications in day hospitalization vs. inpatient surgery for surgeries such as cataract surgery or elective laparoscopic cholecystectomy [5,8,11]. In other words, day hospitalization does not increase but the rate of postoperative complications does not decrease. The surgical gesture, as well as the anesthesia, especially the general anesthesia in the case of abdominal or pelvic surgery, is an aggression for the body. In the case of the option for day-care surgery, the possible complications or side effects must be known and counteracted efficiently in order not to induce a major physical or mental discomfort to the patient after discharge [9,13].

Even if the procedure is approved for day-surgery, the patient's general condition and associated co-morbidities must be thoroughly analyzed during the preoperative consultation. General anesthesia

and laparoscopy, by insufflating CO_2 to create pneumoperitoneum, create cardiovascular and respiratory imbalances that can be easily compensated in 1-2 hours in a normal subject, but which can generate respiratory acidosis, hypercapnia, with heart rhythm disorders and acute myocardial ischemia. In people with pre-existing cardiovascular or lung conditions [17-20]. These adverse events can occur in the elderly, even without apparent major outcomes, due to age-related general frailty, which generates an increased vulnerability in these patients [17, 21,22].

Schillaci *et al.* [2]. showed the important role of the anesthetist in ensuring patient safety in day care surgery centers. An effective non - parenteral protocol for control of pain, nausea and vomiting is an essential component in a day - case laparoscopic cholecystectomy service [23].

Postoperative pain is one of the main factors of postoperative discomfort and worry in the first postoperative evening [9, 23,24]. The subjectivism of the intensity of this pain is of course an important factor [25]. However, the patient should be presented with an efficient postoperative pain management plan that preferably does not include parenteral medication. The patient should also be warned about the type and severity of the expected pain and those signs that may suggest a complication that would require an emergency presentation for surgical reassessment. For example, in the case of laparoscopic cholecystectomy, the intensification of pain could have the significance of a biliary complication [5,26,27].

The choice of anesthetic technique can have a significant effect on post-operative recovery and discharge. The anesthesia should be chosen to have the minimal disturbance on the patient and maximum effect. Besides general anesthesia, in ambulatory settings, there is an increase emphasis on regional anesthesia, multimodal approach and monitored anesthesia care [15-17].

A significant side effect of general anesthesia is postoperative nausea and vomiting (PONV) which can be very disturbing to the patient [28-30]. Numerous factors may be involved: factors related to the patient (young patients <50 years, women, non-smokers, suffering from motion sickness), duration (> 30 minutes) and type of surgery (cholecystectomy, gynecological surgery), type of substances used to induce and maintain anesthesia, pain or early postoperative mobilization may be triggers for POVN. Careful anesthetic evaluation can identify those predisposed individuals and take measures to prevent and combat POVN by pharmacological and non-pharmacological means, starting from the preoperative period [28]. A multimodal approach to reduce PONV consisting of preoperative anxiolysis (midazolam), prophylactic antiemetics, and local anesthetic infiltration avoiding anesthetic drugs associated with increased risk of nausea and vomiting (nitric oxide, high dose of opioids) as well as prompt rescue therapy is recommended in day surgery [27-29]. The evaluation of the anesthetist at 4-6 hours postoperatively will decide if the patient is fit to be discharged.

Patient preparation

Informing patients is particularly important, as they will become an active partner in the patient-physician relationship in preoperative training and postoperative care. Due to the very short time, this cannot be done on the day planned for the operation, but must be performed during a previous consultation. The information of the patient must be made verbally but also by printed means. The signing of informed consent should be followed by a discussion of the technique, risks, benefits and most common postoperative complications and how they should react if they occur. An adequate care provider should assist the patient for at least the next 24 hours [9, 16,17].

The patient should be instructed about continuing or discontinuing certain personal medication for associated co-morbidities, as well as all the necessary preoperative preparations. At discharge, written instructions are given regarding medication, pain management, special cautions and the schedule of follow-up visits [30-32].

Patients' selection for day care surgery

Great attention must be paid to the proper selection of patients who can benefit from day-care surgery, in this sense a very important role is played by the decision of the anesthetist. When deciding whether a patient is acceptable for day surgery, multiple factors should be taken into account, to minimize the risk of medico-legal issues: who will perform the surgery, where the day surgical procedure will be held (e.g. in a hospital, with the possibility of transfer to inpatient care or in a private day center), what kind of anesthesia is required and who will be responsible, as well as the patient related factors [16,17, 33-36]. Day surgery requires experienced doctors for a certain procedure, which ensures minimal tissue trauma and a low rate of complications. The general selection of patients fit for day-care surgery will take into account social and medical factors.

Patients and their carriers must understand and consent that after general anesthesia or sedation, a responsible person must escort and that care for the patients for the following days. The patient's home must be within a reasonable distance (1 hour, 20-25 km) from the medical center, must have access to telephone, running water, central heating and may allow easy access for emergency aid in case of necessity [8,9,16,37,38]. The patient must return assisted in the following day for the medical control. From the medical point of view, patient's age, BMI, ASA score and comorbidities must all be taken into account [13,15, 34,35].

The importance of patients 'selection extends to patient management as a whole. Generally, for day surgery the patients with ASA below 3 are selected [13-15, 32]. Chronic stable diseases, like diabetes, asthma or arterial hypertension, are not contraindications, but must be carefully managed pre- and post-operatively [33-36]. There is not a distinctive age limit for day surgery. On one hand, several studies showed that early returning after surgery in the familiar environment decreased the cognitive impairment in the elderly. On the other hand, the age-related frailty and possible associated comorbidities, might led surgeons to prefer inpatient treatment in advanced ages. Kataria *et al.* [17] showed that cardiovascular events, such as hypertension, hypotension, and arrhythmia are more frequent in elderly, while other adverse events, like postoperative pain and PONV are less encountered.

Outcomes of day surgery

Several studies regarding the outcomes of day surgery found that the unexpected admissions within the first 24 hours after surgery varied between 0.03–4 %, mainly caused by bleeding, pain or drowsiness, and in 2% of cases the visits to the emergency department were not followed by readmission. The average rate of complications was found to be around 2 %, the most frequent being: bleeding, infected wounds, sepsis and thrombosis) and overall, 0–0.01 % of the patients died [26,27,35]. Efficient and comprehensive surveillance of outpatient surgical care is necessary to fully identify opportunities to improve patient safety.

Implementing day surgery in current surgical practice could decrease significantly the expenses in the medical care. However, surgeons need to correctly identify the patients fitted for outpatient management, to prevent medico-legal issues. From the patients' perspective, several psychosocial factors affect the acceptance of early discharge: anxiety about the surgery done and the possibility of developing complications, postoperative pain, difficulty related to transport or health care facility nearby and the lack of a care giver at home [4, 9, 25].

In conclusion, under the pressure of economic efficiency of medical care, day care surgery is a growing concept which should be considered more frequent in the clinical practice, in all surgical specialties. While obviously not all the procedures could be performed on daily basis, there is clinical evidence that day surgery is safe and effective in elective cases, with an anticipated simple outcome, and in well selected patients. The degree of difficulty encountered during an operation can often be difficult to predict. A complete preoperatory evaluation, as well as detailed information previous obtaining informed consent are extremely important to increase the safety and minimize the risk of adverse events in outpatient surgery.

Conflict of interest

The authors declare that they have no conflict of interest.

References

1. Editorial. Br Med J 1948: 2: 1026.
2. Schillaci DR, Pellegrinelli M, Morini O. Day surgery: medico legal aspects. Minerva Medicolegale. 2004;124(1):23-32.
3. Mulchandani DV. Medicolegal Issues in Day Care/Ambulatory Surgery. In: Begani M, Mulchandani D, Choudhary S. (eds) Anesthesia in Day Care Surgery. Springer, Singapore. 2019.
4. Weingessel B, Wahl M, Vécsei-Marlovits PV. More frequent requests for day-case cataract surgery : An impressive mind switch in the Austrian population within 7 years. Wien Med Wochenschr. 2017;167(13-14):314-319.
5. Lawrence D, Fedorowicz Z, van Zuuren EJ. Day care versus in-patient surgery for age-related cataract. Cochrane Database Syst Rev. 2015;2015(11):CD004242.
6. http://legislatie.just.ro/Public/DetaliiDocument/225924.
7. Weingessel B, Richter-Mueksch S, Weingessel A, Gnad H, Vécsei-Marlovits PV. Is day-case cataract surgery an attractive alternative from the patients' point of view? A questionnaire survey. Wien Klin Wochenschr. 2008;120(23–24):756–760.
8. Majholm B, Engbæk J, Bartholdy J, Oerding H, Ahlburg P, Ulrik AM, Bill L, Langfrits CS, Møller AM. Is day surgery safe? A Danish multicentre study of morbidity after 57,709 day surgery procedures. Acta Anaesthesiol Scand. 2012;56(3):323-331.
9. Lemos P, Jarrett P, Beverly P: Day Surgery: Development and practice, Classica artes grafica, Porto, 2006, www.iaas-med.org, ISBN 978-989-20-0234-7.
10. Fischer, S., Zechmeister-Koss, I. Is day surgery safe? A systematic literature review. Eur Surg. 2014; 46:103–112.
11. Nisha B, Lionel KR, Unnikrishnan P, Praveen R, Hrishi AP. Day care neurosurgery in India: Is it a possible reality or a far-fetched illusion? A neuroanesthesiologist's perspective. Neurol India [serial online] 2019 [cited 2020 Dec 12];67:938-941. Available from: https://www.neurologyindia.com/text.asp?2019/67/3/938/263216
12. Vilanilam GC, Hari VS. "Going home the same day"-Is day care neurosurgery a measure of surgical skill and technical advancement? Neurol India. 2017;65:228-230.

13. Gurusamy K, Junnarkar S, Farouk M, Davidson BR. Meta-analysis of randomized controlled trials on the safety and effectiveness of day-case laparoscopic cholecystectomy. Br J Surg. 2008;95(2):161–168.
14. Qadir N, Smith I. Day surgery: how far can we go and are there still any limits? Curr Opin Anaesthesiol. 2007; 20: 503– 507.
15. Kulkarni S, Harsoor SS, Chandrasekar M, Bhaskar SB, Bapat J, Ramdas EK, Valecha UK, Pradhan AS, Swami AC. Consensus statement on anaesthesia for day care surgeries. Indian J Anaesth. 2017;61:110-124.
16. Darwin L, Chung F: Patient selection for day surgery, Anaesthesia & Intensive Care Medicine. 2013; 14(3):114-118.
17. Kataria T, Cutter TW, Apfelbaum JL. Patient selection in outpatient surgery. Clin Plast Surg. 2013;40(3):371-382.
18. Demyttenaere S, Feldman LS, Fried GM. Effect of pneumoperitoneum on renal perfusion and function: a systematic review. Surg Endosc. 2007;21(2):152-160.
19. Atkinson TM, Giraud GD, Togioka BM, Jones DB, Cigarroa JE. Cardiovascular and Ventilatory Consequences of Laparoscopic Surgery. Circulation. 2017;135(7):700-710.
20. Westerband A, Van De Water J, Amzallag M, Lebowitz PW, Nwasokwa ON, Chardavoyne R. Cardiovascular changes during laparoscopic cholecystectomy. Surg. Gynecol. Obstet. 1992;175(6):535–538.
21. Garcea G, Majid I, Pattenden CJ, Sutton CD, Neal CP, Berry DP. Predictive factors for unanticipated admission following day case surgery. Journal of Evaluation in Clinical Practice. 2008; 14: 175-177.
22. Mull HJ, Itani KMF, Pizer SD, Charns MP, Rivard PE, McIntosh N, Hawn MT, Rosen AK. Development of an Adverse Event Surveillance Model for Outpatient Surgery in the Veterans Health Administration. Health Serv Res. 2018;53(6):4507-4528.
23. Tenconi SM, Boni L, Colombo EM, Dionigi G, Rovera F, Cassinotti E. Laparoscopic cholecystectomy as day-surgery procedure: current indications and patients' selection. Int J Surg. 2008;6 Suppl 1:S86-88.
24. Tebala GD, Belvedere A, Keane S, Khan AQ, Osman A. Day-case laparoscopic cholecystectomy: analysis of the factors allowing early discharge. Updates Surg. 2017;69(4):461-469.
25. Vijayakumar C, Elamurugan TP, Sudharsanan S, Jagdish S. Factors Hindering Practice of Day Care Surgery in a Tertiary Care Centre in Southern India: A Patient's Perspective. J Clin Diagn Res. 2017;11(6):PC05-PC07.
26. Barthelsson C, Anderberg B, Ramel S, Björvell C, Giesecke K, Nordström G. Outpatient *versus* inpatient laparoscopic cholecystectomy: a prospective randomized study of symptom occurrence, symptom distress and general state of health during the first post-operative week. J Eval Clin Pract. 2008;14(4):577–584.
27. Xiong W, Li M, Wang M, Zhang S, Yang Q. The Safety of Laparoscopic Cholecystectomy in the Day Surgery Unit Comparing with That in the Inpatient Unit: A Systematic Review and Meta-Analysis. Biomed Res Int. 2020;2020:1924134.
28. Shaikh SI, Nagarekha D, Hegade G, Marutheesh M. Postoperative nausea and vomiting: A simple yet complex problem. Anesth Essays Res. 2016;10(3):388-396.
29. Chandrakantan A, Glass PS. Multimodal therapies for postoperative nausea and vomiting, and pain. Br J Anaesth. 2011;107(Suppl 1):i27–40.
30. Raveesh BN, Nayak RB, Kumbar SF. Preventing medico-legal issues in clinical practice. Ann Indian Acad Neurol. 2016;19(Suppl 1):S15-S20.
31. Ramyil VM, Iya D, Ogbonna BC, Dakum NK. Safety of daycare hernia repair in Jos, Nigeria. East Afr Med J. 2000;77(6):326–328.
32. Vaughan J, Gurusamy KS, Davidson BR. Day-surgery versus overnight stay surgery for laparoscopic cholecystectomy. Cochrane Database Syst Rev. 2013;(7):CD006798.
33. Manzia TM, Quaranta C, Filingeri V, Toti L, Anselmo A, Tariciotti L, De Carolis G, Cacciola R, Di Lorenzo N, Sorge R, Angelico R, Monteleone G, Tisone G. Feasibility and cost effectiveness of ambulatory laparoscopic cholecystectomy. A retrospective cohort study. Ann Med Surg (Lond). 2020;55:56-61.
34. Ahmad NZ, Byrnes G, Naqvi SA. A meta-analysis of ambulatory versus inpatient laparoscopic cholecystectomy. Surg Endosc. 2008;22(9):1928–1934.
35. Tang H, Dong A, Yan L. Day surgery versus overnight stay laparoscopic cholecystectomy: A systematic review and meta-analysis. Dig Liver Dis. 2015;47(7):556-561.
36. Mattila A, Mrena J, Kautiainen H, Nevantaus J, Kellokumpu I. Day-care laparoscopic cholecystectomy with diathermy hook versus fundus-first ultrasonic dissection: a randomized study. Surg Endosc. 2016;30(9):3867-3872.
37. Zhuang M, Fan W, Xie P, Yuan ST, Liu QH, Zhao C. Evaluation of the safety and quality of day-case cataract surgery based on 4151 cases. Int J Ophthalmol. 2019;12(2):291-295.
38. Grzybowski A, Kanclerz P. Do we need day-1 postoperative follow-up after cataract surgery? Graefes Arch Clin Exp Ophthalmol. 2019;257(5):855-861.