



Original Article

A ten-year analysis of the reasons for death following ambulatory surgery: Nine closed claims declared to the SHAM insurance

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ABSTRACT

Introduction: The constant development of ambulatory surgery (AS) raises the problem of monitoring patients after discharge and the risk of death in the case of delays in the management of a serious complication.

Patients and methods: The aim of this retrospective study was to describe the deaths observed within the 30-day period following AS declared to the SHAM insurance (*Société hospitalière d'assurance mutuelle*) over the last 10 years.

Results: During the study period 33,962 claims were surgery-related and 11 were for deaths after AS. Two of the death claims were excluded from our study because they occurred after the first month. The surgeries concerned were tonsilectomy (3), cataract (2), inguinal hernia (2), varicose vein stripping (1) and laparoscopy (1). Death occurred on average 5.4 days after the AS, in intensive care (3), during hospitalisation (2), with emergency medical services (1), in an emergency department (1) or at home (2). Anaesthesia was directly implicated in 3 cases: anaphylactic shock (Diamox), pneumoperitoneum (gastric swelling) and hemoperitoneum (mismanagement of anticoagulants). 1 case was due to a pulmonary embolism and 5 to a surgical cause.

Discussion–conclusion: There was only one case where the complication was aggravated due to the delay of care provision and this was because of a lack of information on the complications requiring an emergency return (abdominal pain after laparoscopy). In all the other cases, death would also probably have occurred during conventional hospitalisation, either because it was unavoidable or because the patient was too far from the surgery.

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1. Introduction

The constant development of ambulatory surgery (AS) and the performance of increasingly complex procedures raise the problem of monitoring patients after their discharge and the potential risk of death by delaying the management of a serious complication.

Studies done on large groups report an extremely low death rate incidence (1 to 2/10,000 within 30 days) that is generally not attributable to outpatient care [1,2].

SHAM (*Société hospitalière d'assurance mutuelle*), is the leading medical liability insurer in France (50% market share), guarantees 80% of public institutions, 25% of private institutions and so is a

very relevant source of information on claims relating to patient care activity in the French market.

The purpose of this study was to identify and describe deaths observed within the 30-day period following AS, due to medical or surgical reasons over the last 10 years.

2. Patients and methods

We performed an observational and retrospective study of the closed claims in AS reported to SHAM over a period of 10 years (2006–2015) that were either settled amicably or in court.

All the records were compiled in the SHAM database (database: declaration of claims). This database includes all claims reported to SHAM on French soil, the information is collected by the disaster managers and the lawyers of SHAM.

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SHAM is a health insurance company specialising in insurance and the management of health risks for healthcare professionals and social and socio-medical personnel. In addition to their activity as an insurer, SHAM is committed to reducing the activity risk of all their healthcare professionals by offering advice and risk and performance management services.

Inclusion criteria were declared claims to SHAM between January 1st 2006 and December 31st 2015, with the death of the patients taken into care for ambulatory surgery and with a hospitalisation stay of less than 12 hours.

Exclusion criteria were patients cared for under a conventional hospitalisation procedure (with a night's stay in hospital) and patients who did not receive surgery (particularly those who had endoscopy procedures).

A search was done in the SHAM database using the keywords « ambulatory surgery ». In this way we were able to extract the claims files that were pertinent to ambulatory surgery and from that point forward all the files were analysed regardless of how a conclusion was reached (amicably, by a conciliation committee and with compensation or judicial). The data remained anonymous concerning the hospital, the physician and the patient's name.

Analysis of these cases was done by two doctors respecting anonymity, one was from the risk management division of SHAM and the other, a hospital anaesthetist, was independent from SHAM. The collected data mixed factual (clinical and demographic characteristics) and interpretative items (results from the experts' evaluations). At the end of the analysis, concordance between the two experts was verified. If there was any discordance, the case in question was collegially reviewed.

Statistical analysis was performed using Microsoft Excel[®] Version 14.3.2. Data is expressed as numbers (*n*) or percentages (%).

3. Results

The number of claims reported to SHAM for medical liability over the 10-year study period was 57,645 of which 33,962 related to surgical activity. Of these, 11 were recorded as death after AS. Two were excluded because they occurred 112 and 163 post-operative days after AS. The mean patient age was 52.7 years (7 adults and two children).

The surgeries concerned were tonsillectomy (3), cataract operations (2), laparoscopic inguinal hernia interventions (2), varicose vein stripping (1) and exploratory digestive laparoscopies (1).

Death occurred on average 5.4 days following the operation (median = 3, min = 1, max = 21), either in the intensive care unit (3), during hospitalisation (2), with the emergency medical services (1), in an emergency department (1) or at home (2). Of the 9 patients, 3 patients were unable to leave ambulatory surgery the day of the surgery; they were hospitalised and died shortly after. [Table 1](#) represents the clinical histories, time of occurrence and causes of death.

The conclusions retained by the medical insurance expert were: a therapeutic risk (3), an absence of any causal link (2), a lack of communication between the anaesthetist and the surgeon which was aggravated by an error in the post-operative paramedical follow-up (1), a failure to take correct care of the complication by the emergency unit (1) and a discharge that was too early and which was also associated with not enough information being given to the patient in the advent of complications requiring his return (1).

Medical care was only directly implicated in three cases: anaphylactic shock (Diamox), pneumoperitoneum following gastric swelling linked to the intranasal oxygen probe and hemope-

ritoneum due to the mismanagement of anticoagulants before the operation (failure in communication). For 5 other cases the cause was surgical and for one case it was a probable massive pulmonary embolism. In one of the cases the cause was medical but the diagnosis remains unclear (probably an acute digestive pathology or an acute adrenal insufficiency).

The cases were all settled before a Conciliation and Compensation Commission and no case was settled by a judicial process.

4. Discussion

After interventions performed in ambulatory surgery, the follow-up care must be simple in order to allow a patient to be discharged the same day without any side effects or complications. However, with this type of care, the practitioners fear that the patients discharged on the same day as their surgical procedure may pose a problem for monitoring and managing any possible complications. The risk of delay in follow-up aftercare in certain extreme cases could lead to the death of the patient.

Our study aimed to analyse deaths occurring after ambulatory surgery for claims taken from the declaration database of the insurance company over a long period. Our research was based on the SHAM claims database. SHAM is the main civil liability medical insurer in France.

Our current results report only 11 deaths over a period of 10 years, among which nine arose within the first 30 days following the surgical procedure. In three cases complications arose very quickly after the procedure and the patient was not able to leave the ambulatory surgical unit. In the other cases, the time of death happened generally several days following the intervention and at a moment in time when hospitalisation was no longer deemed necessary.

The only case of an intervention causing death due to its ambulatory nature and thus entailing a delay in follow-up aftercare, was the one of a 66-year-old patient who underwent surgery for an exploratory digestive coelioscopy. The undesired event that caused her death was an intraoperative lesion of the small intestine that went unnoticed.

The first aggravating factor was that the patient had not been correctly informed of the warning signs to look for following this surgery that would require her to return for a consultation. The second aggravating factor was that during two conversations with the patient on the first pre-operative night, the paramedics of the surgical ward did not take into account the existence of the warning signs requiring her to return for consultation. This is subsequently the only case where the patient's early discharge led to a delay in follow-up care and consequently the ambulatory nature of this intervention is directly and definitely related to the patient's death.

In three cases death occurred after a tonsillectomy, including two cases related to severe haemorrhaging, following the scab falling off in children. The question of the necessary hospitalisation duration for monitoring purposes is regularly discussed in research papers and within learned societies, as tonsillectomy is responsible for a high mortality rate. The Majholm study reports that it is the outpatient procedure for which the rate of return for consultation is the highest [2]. Bleeding is a complication that can occur in 3 to 15% of cases depending on the series analysed and between the 3rd and 8th post-operative days [3,4]. The mortality rate after tonsillectomy is estimated at 1/40,000 mainly due to haemorrhaging [5]. In France, it is recommended to choose ambulatory surgery if the eligibility criteria are favourable (ASA 1 or 2, there's an absence of comorbidities that increase respiratory risk and the absence of haemostasis syndromes) [6]. In our study bleeding occurred on D3 in one case and D7 in the other, the outpatient

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