Case report writing sample work

A CASE STUDY ON THE EFFECTIVENESS OF RECOVERY FOR PATIENTS UNDERWENT LAPAROSCOPIC WEIGHT LOSS SURGERY

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INTRODUCTION

Morbidly obese patients undergoing laparoscopic bariatric surgery are particularly vulnerable to post-operative complications and require specifically tailored anaesthetic procedures[1].

The administration of a neuromuscular blocking agent (NMBA) facilitates patient ventilation during surgery, prevents involuntary movements by the patient and enhances surgical exposure. Rucuronium, an aminosteroid and cisatacurium, a benzylisoquinone compound are two commonly used neuromuscular blocking agents with different molecular and pharmacological properties[4]. When surgery has been completed, reversal of NMBA activity allows patients to breathe independently and resume normal muscle function. Acetylcholine inhibitors like neostigmine or an amionsteroid encapsulating agent like sugammadex are used to rapidly reverse NMB agents. Rapid reversal of neuromuscular blockade after surgery is desirable to avoid postoperative residual curarization (PORC) which can lead to potentially fatal respiratory problems. Rapid and reliable reversal of NMB agents also improves pain management, patient comfort and recovery[3,5,6].

Several studies have reported favourable outcomes with the use of sugammadex for the recovery of neuromuscular functions in morbidly obese patients[7–9]. In a randomised controlled trial comparing the effects of sugammadex and neostigmine in patients undergoing laparoscopic surgery, 94% (n=66) of patients treated with sugammadex recovered within 5 minutes compared with 20% (n=65) of patients treated with neostigmine[8].

Despite encouraging evidence on the efficacy and safety of sugammadex, clinicians and healthcare resource managers require justification for the greater cost of this drug. One such justification may be the impact of this drug on the quality of post-surgical recovery of patients.

Case study process

Selection of appropriate NMB reversal agents plays an important role in managing successful post-surgical recovery of morbidly obese patients. With rising number of obese patients in the UK,

surgical departments are increasingly under pressure to improve services, increase efficiency and also save money[10]. A study of the various anaesthetic procedures and the quality of recovery of morbidly obese patients following bariatric surgery will inform crucial decisions about surgical treatment pathways and help decrease post-surgical recovery times.

Proposed Title And Case Study Direction.

Title: A prospective study to describe the quality of recovery of morbidly obese patients following laparoscopic bariatric surgery

To describe:

- The recovery process of morbidly obese patients following laparoscopic bariatric surgery
- The anaesthetic procedures used in laparoscopic bariatric surgery for morbidly obese patients
- The demographic and clinical characteristics of patients undergoing laparoscopic bariatric surgery

METHODOLOGY

This is a prospective observational study of morbidly obese patients who undergo laparoscopic bariatric surgery across the operating suites at three hospital sites in the UK over a period of 3 months. The choice of a prospective study model is to allow real-time documentation of surgical and anaesthetic procedures and post-operative recovery of patients at each hospital site.

Anonymized data will be collected both retrospectively from a review of the patient's medical notes to determine the underlying diagnosis, medications taken and clinical characteristics, and prospectively from the point of administration of general anaesthesia prior to the operation to when they are transferred to the ward following surgery.

Data will be collected by nominated members of the NHS theatre team, recovery unit team, and ward staff at the point of care to minimize observer bias. Data will be collected directly onto paper data collection forms before being transcribed into an electronic database.

- **Study Population**
- The study population will include 120 morbidly obese patients undergoing laparoscopic bariatric surgery in three hospital sites in the UK over a period of three months.
- **Inclusion Criteria**
- Morbidly obese patients (BMI 40kg/m^2 or above) who are undergoing laparoscopic bariatric surgery
- Age 18 or over at the time of surgery
- Exclusion Criteria
- Patients whose medical records are unavailable
- Patients that either refuse or lack capacity to provide written informed consent
- Patients with conditions that contraindicate the use of NMBA

STUDY PROCEDURES

Written informed consent will be obtained from each patient before for enrolment in this study. No study data will be collected from any patients unless written consent has been provided.

Written informed consent will be sought by either members of the hospital research and development department or by members of the direct care team. Patients will be provided a copy of the information sheet detailing the study and its requirements. Adequate time will be granted to patients so that they have an opportunity to read the information sheet and to ask questions before any decision to take part is made and written consent sought.

A copy of the signed consent form will be maintained by the study investigator at each participating centre in the study site file.

Primary Data Collection

The assessment of causality is to be determined by an investigator who is a qualified healthcare professional according to his/her best clinical judgment. Use the following criteria as guidance (not all criteria must be present to be indicative of causality to a Sponsor's product): There is evidence of exposure to the Sponsor's product; the temporal sequence of the AE onset relative to

the administration of the Sponsor's product is reasonable; the AE is more likely explained by the Sponsor's product than by another cause.

Secondary Data Collection

Only AEs with an explicit and definitive notation (by a healthcare provider) of a causal relationship with a product in the medical records or other secondary data being reviewed should be reported as NSAR/SARs. During review of secondary data, causality should never be assigned retrospectively

STATISTICAL METHODS

All analyses will be descriptive in nature. Both distributions and descriptive statistics of both central tendency (medians and arithmetic or geometric means) and dispersion (standard deviation, interquartile range) will be presented for quantitative variables. Nominal variables will be described with frequencies and percentages while ordinal variables will also have medians and interquartile ranges described.

ADMINISTRATIVE AND REGULATORY DETAILS

Confidentiality of Data

By signing this protocol, the investigator affirms to the Sponsor that information furnished to the investigator by the Sponsor will be maintained in confidence, and such information will be divulged to the Institutional Review Board, Ethics Review Committee or similar or expert committee; affiliated institution and employees, only under an appropriate understanding of confidentiality with such board or committee, affiliated institution and employees. Data generated by this study will be considered confidential by the investigator, except to the extent that it is included in a publication as provided in the Publications section of this protocol.

Confidentiality of Subject Records

By signing this protocol, the investigator agrees that the Sponsor (or Sponsor representative), Institutional Review Board/Independent Ethics Committee (IRB/IEC), or Regulatory Agency representatives may consult and/or copy study documents in order to verify worksheet/case report form data. By signing the consent form, the subject agrees to this process. If study documents will be photocopied during the process of verifying worksheet/case report form information, the

subject will be identified by unique code only; full names/initials will be masked prior to transmission to the Sponsor.

PUBLICATIONS

Study results will be disseminated as posters or oral presentations at appropriate clinical conferences, to be identified at the start of the study in collaboration with by clinical experts. The results will also be published in an end of study report for the Sponsor and submitted as a paper to a peer-reviewed academic journal.

References

1. Nightingale, C. E. *et al.* Peri-operative management of the obese surgical patient 2015. *Anaesthesia* 70**,** 859–876 (2015).

2. Ogunnaike, B. O., Jones, S. B., Jones, D. B., Provost, D. & Whitten, C. W. Anaesthetic considerations for bariatric surgery. *Anesth. Analg.* 95, 1793–1805 (2002).

3. Green, M. S., Venkatesh, A. G. & Venkataramani, R. Management of Residual Neuromuscular Blockade Recovery: Age-Old Problem with a New Solution. *Case Rep. Anesthesiol.* 2017**,** (2017).

4. Appiah-Ankam, J. & Hunter, J. M. Pharmacology of neuromuscular blocking drugs. (2004).

5. Hayes, A. H., Mirakhur, R. K., Breslin, D. S., Reid, J. E. & McCourt, K. C. Postoperative residual block after intermediate-acting neuromuscular blocking drugs. *Anaesthesia* 56, 312–318 (2001).

6. Brueckmann, B. *et al.* Effects of sugammadex on incidence of postoperative residual neuromuscular blockade: a randomized, controlled study. *Br. J. Anaesth.* 115, 743–751 (2015).

7. Abrishami, A., Ho, J., Wong, J., Yin, L. & Chung, F. Sugammadex, a selective reversal medication for preventing postoperative residual neuromuscular blockade. *Cochrane Database Syst. Rev.* (2009). doi:10.1002/14651858.CD007362.pub2

8. Geldner, G. *et al.* A randomised controlled trial comparing sugammadex and neostigmine at different depths of neuromuscular blockade in patients undergoing laparoscopic surgery*. *Anaesthesia* 67, 991–998 (2012).

9. Gaszynski, T., Szewczyk, T. & Gaszynski, W. Randomized comparison of sugammadex and neostigmine for reversal of rocuronium-induced muscle relaxation in morbidly obese undergoing general anaesthesia. *Br. J. Anaesth.* 108, 236–239 (2012).

10. Obesity: identification, assessment and management | Guidance and guidelines | NICE. Available at: https://www.nice.org.uk/guidance/cg189. (Accessed: 4th June 2017)