Commentary: Ambulatory Surgery Centres are Well Suited for Clinical Research

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Introduction

The health care industry has witnessed a substantial rise in the volume of surgeries and medical procedures being performed in ambulatory surgical centres [1]. While this shift in surgical management often has been linked to technological improvements and an enhancement of administration of anaesthetic drugs, as well as the need to reduce the overall costs of medical treatment, it has also brought forward a shift in patient management and the possibility of monitoring patient progress in clinical trials.

Traditionally we are used to clinical trials in an in-patient setting with volunteers often waiting days or weeks for the approval and implementation of a planned procedure. The planned activities will be subject to delays due to a multitude of reasons; emergency cases taking priority in the OR, lack of OR staff members, hospital policy or a depletion of hospital funding. In addition, there will be a variety of medical professionals involved. This implies that people with different sets of surgical skills and medical know how to perform the actual treatment. Unless the number of patients treated in the trial is substantially high, this will create a bias in the measured outcome. Chowdhury and co-workers reflect on this in a systematic review in the British Journal of Surgery in 2007, in which over 55000 articles were reviewed between 1957 and 2003, where they conclude that high surgeon volume and specialization are associated with improvement in patient outcome [2]. In addition to this ambiguous setting, the cancellation of elective surgery in tertiary level hospitals may still be high in a global perspective with up to one fifth of scheduled cases being postponed on the day of surgery [3].

Why are ambulatory surgery centres well adapted to clinical research?

In the ambulatory surgery centre the elective surgery is made a priority, and scheduled surgery will usually go as planned due to reliable patient pre-assessment plans [4] and a minimum of interference from outside the operating room. The benefit of treating otherwise "healthy" patients with little or no co-morbidities is an obvious cause of controlling research confounding.

This creates an ideal environment for real life clinical research trials. In contrast to large hospital based trials that need to single out certain traits or construct a specific scenario in which two or more treatments are compared, the ambulatory surgery trials will focus on quality assessments and clinical parameters that are not constructed for the sake of a research project. In this regard, ambulatory research has an aura of quality assessment about it and the results are usually very reliable due to small teams with one or two specialized surgeons, a dedicated staff in both the OR and the recovery room that has extensive experience in the procedures that are performed. Furthermore, the ambulatory centres have made elective surgery a clear priority with few unexpected procedure dropouts or cancellations on the day of the surgery [5].

What types of research are suitable in such a setting? I think it is fair to say that interventions that are time consuming or revolves around patients with rare diseases that generate extra hours of labour for the staff at hand are less suited for ambulatory research. Large observational case-control studies and time consuming prospective cohort studies are probably difficult to conduct due to the amount of follow up time required by such studies. The ambulatory setting will rather attract those type of studies where the intimate relationship between the patient population and the researchers facilitates a better coordination than what can be achieved in a large scale hospital setting. Put simply, the ambulatory setting offers a more streamlined approach to clinical real life research due to greater control over procedures and patient logistics. Experimental interventional studies that involve pre- and postoperative medical interventions, randomized prospective trials involving medical or surgical interventions or trials of new technology/innovations within the pre-, per- or postoperative phase can be done reliably, relatively quickly and without spending the entire department budget in doing so.

In my department there are a total of four operating rooms, and the recovery unit can handle around fifteen patients when all the ORs are in use. There are three research projects currently running. Two prospective trials within ENT [6, 7] and one randomized controlled and prospective trial on hypothermia during surgery (data not yet published). Up to this point, all patients have had their procedures done without prolonging the pre- or postoperative time spent at the daycare unit. The main reason for the seemingly effortlessly patient logistics is in my opinion the less institutionalized environment and the high volume of same surgery procedures that keep the staff well prepared and trained at all times.

Future concerns?

Are there any concerns that should be addressed? Of course there is the matter of financing. There is no shortage of funding institutions, but so far there seems to be a tendency to give credits to the already established research communities affiliated with university clinics, making it harder for smaller ambulatory centres to get grants. Some private ambulatory hospitals have solved this by setting aside part of their revenue to establish their own research fund in accordance with the rules of good clinical research practice (GCP). Aleris Hospital, Scandinavia's largest chain of private health care companies, made a trial research fund of 1 million pounds from 2013-16 which became an instant success. This year the fund was made permanent, donating 250 000 pounds a year to applicants that fulfil the guidelines of GCP.

Another concern is the time the researchers themselves spend on documenting the projects. The researchers are usually members of the staff, doctors or nurses that spend some of their free time on their projects. Even though some clinics have established grants enabling their staff to do research, there is still a lack of standardized protocols within the ICT systems that can facilitate outcome measures and make it easier to collect biometric information.

Conclusion

Ambulatory surgery centres are ideal for real life clinical research given that the funding of the research is established. Experimental studies, both non-randomized and randomized, can be performed due to high surgeon volume and smaller settings that are key to improved efficacy and good clinical trials.

Key points

- Experimental studies suitable for ambulatory surgery centers, less suited for large scale observational studies on rare diseases
- High surgeon volumes and specialized staff of key importance
- There is a lack of reliable funding for researchers as well as reliable ICT systems for research purposes

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