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Original research

The IDEAL prospective development study format for reporting surgical innovations. An illustrative case study of robotic oesophagectomy

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HIGHLIGHTS

- This paper demonstrates the use of the IDEAL Prospective Development Study format for presenting early work on surgical procedures.
- We show how transparency in reporting changes during development can allow others to benefit from the authors experience.
- The findings are of special interest to upper GI surgeons interested in using a robotic approach for oesophageal resection.

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ABSTRACT

Background: The early development of innovative surgical procedures is usually reported as retrospective case series, wasting opportunities to provide useful information and introducing bias. We present a report of an innovative procedure in development, using the Prospective Development Study (PDS) format recommended by the IDEAL Collaboration.

Methods: We report the development of robotically assisted oesophagectomy by a two-surgeon team from the first robotic case onwards. Key outcomes (blood loss, robotic operating time, lymph node yield, length of stay and complications) are prospectively reported for each patient sequentially. Reasons for rejecting cases for robotic surgery are explained. All changes to technique or indication are highlighted, showing when they occurred and explaining why they were instituted.

Results: The first robotic oesophagectomy was attempted in December 2009. Subsequently 55 oesophagectomies were undertaken, 34 using the robot and 21 without it. Seven deliberate changes in technique occurred during the series. Nodal yield increased markedly after adopting formal mediastinal node dissection and clipping of the thoracic duct. No obvious trends were noted in other outcomes. The robot facilitated Intra-thoracic anastomosis, but mediastinal node dissection showed no advantages due to loss of haptic sensation. Complication rates, R0 rates and nodal yield were considered acceptable.

Discussion: Presenting the development experience in this way improved the clarity of transmission of the main learning points for other surgeons, eliminated bias from selective reporting and explained other types of selection bias. The IDEAL Prospective Development Study has clear advantages over standard case series format for presenting uncontrolled early study data from innovative procedures.

1. Introduction

It has been recognised in recent years that designing and conducting valid scientific evaluations of new surgical and interventional treatments is intrinsically challenging. The nature of the difficulties facing investigators has been extensively discussed [1,2] and a structure for describing the natural history of

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surgical innovation, the IDEAL Framework, has been widely recognised [3]. Recommendations have been proposed for study design and reporting in each of the stages of this Framework, which are intended to match evaluation approaches to the particular problems and questions which arise at each stage. Whilst some of these Recommendations, such as the use of alternative approaches to consent and randomisation in randomised trials, are already widely accepted, others are novel and their practical value therefore remains uncertain through lack of empirical or experiential evidence of benefit. One of the most important of these is the Prospective Development Study (PDS) format, which is recommended by the IDEAL Collaboration for reporting early studies in the Development stage of the IDEAL Framework (see Table 1) when the technique is still in a phase of rapid iterative change [4]. In order to maximise the value of the information to the reader, it is proposed that prospective cohort studies of this type should be completely transparent about patient selection and modifications of technique and indication, presenting all cases in sequence to provide maximum clarity about changes in technique and outcome over time. Although supported by some persuasive arguments, this type of study format has rarely been used to date, so its true value remains empirically untested. We present an example of this study format to facilitate discussion of its potential advantages in reporting early stage innovations in surgery.

The development of minimally invasive surgery for oesophageal cancer (MIO) has been slow, despite the obvious potential benefits. The technical difficulties of performing a resection, lymphadenectomy and anastomosis in a minimally invasive fashion led initially to very long operating times [5] [6], reports of unusual and serious complications [7] [8] [9] and concerns over the oncological adequacy of resections. In more recent years, improvements in the general level of laparoscopic surgery skills and in the technology available have led to renewed interest in MIO. A recent landmark randomised trial has shown a major benefit over open surgery in the rate of post-operative pneumonia [10], and if longer term follow-up confirms oncological adequacy, MIO is likely to become accepted as part of standard care in the near future.

However technical concerns remain, particularly around the dissection in the mediastinum and the performance of intrathoracic anastomosis. Current techniques are reported as difficult by most experts [11–14], and some solutions such as auxiliary minithoracotomy compromise the potential benefits of MIO. These technical difficulties suggest a possible role for robotic surgery. The Da Vinci robot supplies magnification, 3D vision, tremor control and greatly superior manipulative capacity compared to conventional MIO instrumentation, and the hand-sewn anastomosis may be inherently superior to a stapled one [15]. We therefore decided to explore the value of robot-assisted MIO. Before we could do a comparative study, however, we needed to arrive at a stable, well defined approach to this procedure, by evaluating its effectiveness, risks and difficulties in our hands, and perfecting our approach to it. The need for such early development studies in surgery, prior to definitive comparisons, has been extensively discussed by the IDEAL Collaboration [3,4]. The current literature on robotic oesophagectomy comprises mainly small case series [16], with a variety of approaches reported, suggesting that the technique is not yet stable, and placing it in the Development (2a) Stage in the IDEAL Framework [4]. In this report we outline our initial experience with Robot-assisted Oesophagectomy, and more specifically Robotic Ivor-Lewis oesophagectomy (RILO) in the Prospective Development Study form recommended by the IDEAL group, and discuss the potential benefits of this approach over conventional case series.

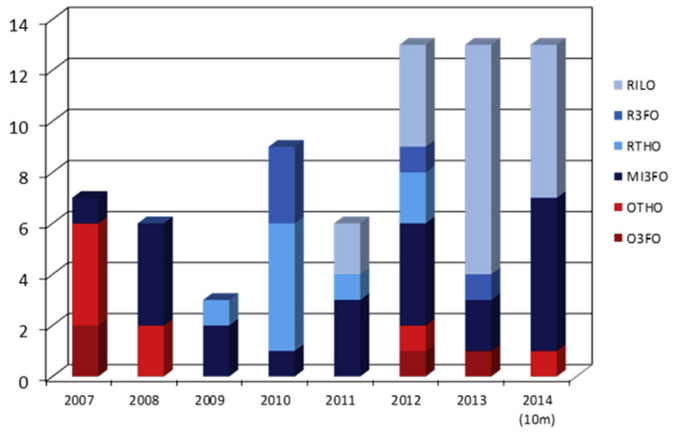

Fig. 1. Evolution from open via MIO to robotic oesophagectomy 2007 to October 2014 (70 cases).

2. Methods

2.1. Preparation and prior experience

The Upper GI surgical team at Basurto University Hospital, Bilbao, began using the Da Vinci robot in September 2009, after training supplied by Intuitive®. Two surgeons appointed in 2007 and 2008 (IDDV and CL) developed their familiarity with robotic surgery in the upper abdomen by doing robotic fundoplications and other operations [17]. Both surgeons had previous experience of advanced laparoscopic surgery and MIO. The Unit also performs around 60 open or laparoscopic gastrectomies a year. Fig. 1 shows the oesophagectomy cases performed by the various approaches in the Unit since 2007, illustrating the transition from open via non-robotic MIO to robotic operation. From December 2007 to 2009, 7 MIO were performed by a 3-field minimally invasive approach involving right thoracoscopy in prone position. Table 2 defines the terminology used to denote the different approaches used during the series.

Table 1
The IDEAL framework.

Stage 1 idea	Stage 2a development	Stage 2b exploration	Stage 3 assessment	Stage 4 long term monitoring
• Initial report • Innovation may be planned, accidental or forced • Focus on explanation and description	• "Tinkering" (rapid iterative modification of technique and indications) • Small experience from one centre • Focus on technical details and feasibility	• Technique now more stable • Replication by others • Focus on adverse effects and potential benefits • Learning curves important • Definition and quality parameters developed	• Gaining wide acceptance • Considered as possible replacement for current treatment • Comparison against current best practice (RCT if possible)	• Monitoring late and rare problems, changes in use & quality of surgical performance