

Prevention of adhesion formation after radical hysterectomy using a sodium hyaluronate–carboxymethylcellulose (HA–CMC) barrier: A cost-effectiveness analysis

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Abstract

Objective. To evaluate the cost-effectiveness of an adhesion prevention strategy compared to routine care, in which no adhesion prevention measures are taken, through a decision analysis model in the clinical setting of patients undergoing radical hysterectomy and pelvic lymphadenectomy for Stage IB cervical cancer.

Methods. A decision analysis model compared two strategies to manage the risk of adhesion-related morbidity following radical hysterectomy for Stage IB cervical cancer: (1) routine care with no adhesion prevention measures, and (2) the intervention strategy with a HA–CMC anti-adhesion barrier. The cost-effectiveness of each strategy was evaluated from the perspective of society and that of a third party payer.

Results. From the perspective of society, the HA–CMC strategy had an overall cost per patient of \$1932 and effectiveness of 7.901 QALYs and dominated the routine care strategy, which had a cost per patient of \$3043 and effectiveness of 7.805 QALYs. From the perspective of a third party payer, the HA–CMC strategy had an overall cost per patient of \$1247 and effectiveness of 7.987 QALYs and dominated the routine care strategy, which had a cost per patient of \$1629 and effectiveness of 7.970 QALYs. A series of one-way sensitivity analyses confirmed the robustness of the model.

Conclusions. Under a conservative set of clinical and economic assumptions, an adhesion prevention strategy utilizing a HA–CMC barrier in patients undergoing radical hysterectomy for Stage IB cervical cancer is cost-effective from both the perspective of society as a whole and that of a third party payer.

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Introduction

Adhesions are fibrous, sometimes vascular bands of scar tissue that connect normally separated organs or tissues and are an almost inevitable result of peritoneal surgery [1]. In a prospective analysis of patients undergoing laparotomy after a

previous abdominal operation, Menzies and Ellis found that 93% of patients had adhesions resulting from their previous surgery, compared to just 10% of patients undergoing first-time laparotomy [2]. Postoperative adhesions are a major source of morbidity following laparotomy and are the most common cause of small bowel obstruction in developed countries [3]. Preceding gynecologic surgery is the second most common cause of adhesive small bowel obstruction (ASBO) after colorectal surgery [3–6]. Ellis et al. surveyed the Scottish National Health Service database and reported that of the 8489 patients undergoing surgery on the female reproductive tract in

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1986, 31.9% (2709) of patients had at least 1 admission during the ensuing 10 years that was directly or possibly related to adhesions [5]. Postoperative adhesion formation represents not only a significant expenditure for the healthcare system but also carries important opportunity costs to society in the form of lost work force capacity and impaired quality of life.

Despite the known burden of adhesions, both surgeons and health care administrators remain unconvinced that the current evidence for adhesion prevention products warrants routine use [7]. The objective of the current study was to evaluate the cost-effectiveness of an adhesion prevention strategy, compared to routine care in which no adhesion prevention measures are taken, through a decision analysis model in the clinical setting of patients undergoing radical hysterectomy and pelvic lymphadenectomy for International Federation of Gynecology and Obstetrics (FIGO) Stage IB cervical cancer. In particular, we sought to determine the potential economic impact of such a strategy both from the perspective of society as a whole and also from the point of view of a third party payer. This specific scenario was selected for study because of the well defined clinical parameters, including adhesion-related morbidity, associated with this patient population.

During the past decade, a variety of commercially available substances and materials have been used in attempts to reduce postoperative adhesion formation. Peritoneal instillates (high-molecular weight dextran, hyaluronic acid, hydrogel, fibrin sealant) have met with variable success [8]. Currently available adhesion barriers include oxidized regenerated cellulose, expanded polytetrafluoroethylene (ePTFE), and hyaluronic acid–carboxymethylcellulose (HA–CMC). Seprafilm® is a bioresorbable HA–CMC membrane that remains where placed and persists in the abdominopelvic cavity for 5 to 7 days. The safety and efficacy of Seprafilm® have been demonstrated in a number of clinical studies of abdominal and pelvic surgery [9–13]. Prospective, randomized trials have demonstrated that Seprafilm® significantly reduces the incidence, severity, and extent of adhesions following two-stage restorative proctocolectomy and uterine myomectomy [9,12,14]. Because the documented performance record of Seprafilm®, compared to other adhesion prevention materials, allowed for straightforward calculations within the decision analysis model, Seprafilm® was adopted as the experimental adhesion prevention strategy in the current study.

Methods

Overall model

A decision analysis model was created to evaluate two strategies to manage the risk of ASBO following radical hysterectomy for FIGO Stage IB cervical cancer. The two strategies were: (1) routine care with no adhesion prevention measures taken at the conclusion of surgery, and (2) the intervention strategy with Seprafilm® anti-adhesion barrier placed to cover the peritoneal defects of the pelvic floor, nodal dissection beds, and abdominal incision. Within each strategy, patients were assumed to have undergone a type III radical hysterectomy and pelvic lymphadenectomy. The principal branch point in the model was at the completion of surgery and defined one arm as the routine care strategy (no adhesion prevention) and the other arm as the Seprafilm® adhesion prevention strategy. Following this branch point, the two arms of the analysis are

identical with the only difference being the probability of ASBO and chronic pelvic pain, depending on whether or not Seprafilm had been placed at surgery. For simplicity, only the routine care arm of the decision analysis model is shown in Fig. 1. Perioperative complications were assumed to be equal between the two strategies.

The model and analyses conform to the 10 basic principles that should be incorporated into a cost-effectiveness analysis identified by the Panel on Cost-Effectiveness in Health and Medicine convened by the U.S. Public Health Service [15]. The base case model was generated from the perspective of society and incorporated all relevant cost associated with adhesive SBO and adhesion-related chronic pelvic pain. Costs to society included: the cost of Seprafilm, direct and indirect costs of hospitalization with professional reimbursement for each episode of adhesive SBO, lost wages, the cost of caregiver support, and lost quality adjusted life years (QALYs) due to hospitalization, recovery time, and death as a result of ASBO. As a secondary outcome, the decision analysis model was revised to reflect the perspective of a third party payer. Third party payer costs included only the direct costs of hospitalization plus professional reimbursement for each episode of ASBO and did not account for lost wages, recovery time, caregiver support, or the impact on quality of life of chronic pelvic pain. The model assumes an initial episode of adhesive SBO during the first year after radical hysterectomy, with recurrent episodes of ASBO occurring at 3 years and 7 years post-radical hysterectomy. The model assumes that chronic pelvic pain will manifest during the first year after radical hysterectomy. Wherever possible, conservative estimates were employed so as not to overstate the potential clinical benefit of the adhesion prevention strategy. All cost estimates and QALY calculations were discounted at a rate of 3% per year.

Model estimates: clinical assumptions

Clinical assumptions were obtained from a review of the published English language literature. Whenever possible, data from phase III trials were utilized; however, when such data were unavailable, clinical assumptions were generated from phase II trials, case control studies, and retrospective case series (Table 1).

Patient age at the time of treatment for cervical cancer was assumed to be 50 years and a 5-year survival rate of 80% was calculated into the QALY estimates [16–18]. The follow-up period extended for 10 years from the time of cervical cancer treatment. The proportion of patients with Stage IB cervical cancer receiving postoperative radiation therapy was assumed to be 35%, based on a 15% incidence of positive pelvic lymph nodes and a 21.3% incidence of high-risk pathological features requiring radiation therapy in lymph node negative patients, as reported by the Gynecologic Oncology Group [19,20]. The proportion of lymph node negative patients receiving adjuvant radiation therapy has been reported to be as high as 35%, such that the overall rate of patients treated with radiation therapy following radical hysterectomy may be as high as 50% [21]. The incidence of ASBO following radical hysterectomy for cervical cancer ranges from 2.4% to 5.0%, while open lower abdominal surgery carries a 7.2% risk of ASBO over 10 years [17,22–25]. For the purposes of the current model, the baseline risk of ASBO after radical hysterectomy was estimated at 4.0%. For patients receiving adjuvant radiation therapy following radical hysterectomy, the risk of ASBO was estimated at 15%, based on literature reports ranging from 14.2% to 20% [17,23,26–28]. Under these assumptions, the model estimate for the overall risk of postoperative ASBO among all patients with Stage IB cervical cancer was 8.0%.

The clinical management of ASBO was structured as a dichotomous branch point within the decision tree and divided into either surgical management or conservative (non-surgical) management. In the literature, the proportion of patients with ASBO undergoing surgical intervention ranges from 23% to 67.7% [3,4,6,29–33]. Clinical data on ASBO were obtained from the Maryland Health Services Cost Review Commission (HSCRC) database for FY 2005 and FY 2006 for the Johns Hopkins Medical Institutions (JHMI) for admissions with a DRG 560.81 (intestinal or peritoneal adhesions with obstruction). Of the 341 patients identified that met study inclusion criteria, 150 patients (44.0%) with ASBO were managed surgically and 191 patients (56%) were treated non-surgically. Consequently, for all ASBO decision nodes within the base case model, it was assumed that patients would receive surgical and non-surgical management at a constant ratio of 45% surgical management and 55% non-surgical management. The reported postoperative mortality following surgical management of ASBO ranges from 1.4% to 9.8% and for the purposes of the

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