OP17 Robotic Versus Conventional Surgery: An Overview Of Systematic Reviews For Clinical Effectiveness With Quality Assessment Of Current Evidence

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Introduction. Robot-assisted surgery (RAS) is being adopted rapidly internationally across a wide range of surgical procedures. Although a great deal of evidence of the clinical effectiveness of RAS has been generated, it is possible that the evidence base is not complete or persuasive in some areas where adoption is being considered. This review seeks to summarize systematic reviews (SRs) undertaken to date to illustrate the weight of evidence across specialties. We then take an in depth look at the quality of evidence across several indications where the adoption of RAS is currently underway.
Methods. A comprehensive literature search was conducted using Ovid Medline, Embase, and Cochrane Central Register of Systematic Reviews from January 2017 to April 2021 for SRs describing clinical effectiveness outcomes. The body of evidence was mapped across all specialties. For a selected number of indications currently under consideration in Scotland, results were comparatively summarized, and the quality of the reviews was evaluated with the AMSTAR-2 tool.
Results. A total of 451 SRs were found. Most were in urology (n = 130) where RAS is well established, followed by colorectal (n = 63), hepatology (n = 58), and gynecology (n = 41). From within these latter three specialties, we selected six indications in which RAS is currently being considered for adoption in Scotland for in depth review (colorectal cancer surgery, hysterectomy, gastrointestinal oncological resection, hepatic, pancreatic and biliary surgery). Evidence for the clinical effectiveness of RAS versus conventional laparoscopic surgery is mixed across indications and outcomes. In colorectal cancer surgery, for example, evidence was positive for conversion rate and neutral for length of hospital stays, blood loss and postoperative complication and negative for operative time. For hysterectomy, evidence was positive for the length of hospital stays and neutral for operative time, blood loss, conversion rate and postoperative complication. The quality of the included reviews was judged to be critically low.
Conclusions. The currently available evidence of clinical effectiveness is mixed across indications and of low quality.

OP18 Clinical Effectiveness And Safety Of Implantable Bulking Agents For Fecal Incontinence: A Systematic Review

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Introduction. The purpose of this systematic review is to evaluate whether implantable versus injectable bulking agents (second-line therapies) are equal/superior in terms of effectiveness (severity, quality of life [QoL], sustainability) and safety (adverse events) for fecal incontinence (FI).
Methods. A systematic review was conducted and five databases were searched (Medline via Ovid, Embase, Cochrane Library, University of York Centre for Reviews and Dissemination, and International Network of Agencies for Health Technology Assessment database). In-/exclusion criteria were predefined according to the PICOS scheme. The Institute of Health Economics risk of bias (RoB) tool assessed studies' internal validity. According to the Grading of Recommendations, Assessment, Development and Evaluation (GRADE) approach, the strength of evidence for safety outcomes was rated. A qualitative synthesis of the evidence was used to analyse the data.
Results. Six prospective uncontrolled trials (143 patients) were included. The evidence consists of six prospective single-arm, before-after studies fulfilling the inclusion criteria for assessing clinical effectiveness and safety for implantable bulking agents. FI severity (Cleveland Clinic FI Score) statistically significantly improved to three months ($p<0.01$) and six months ($p<0.05$) follow-up (five studies). Improvements in severity sustainability were reported after 12, 14 ($p<0.01$), and 36 ($p<0.0001$) months postoperatively. Improved disease-related QoL (FI QoL Score) was found ($p<0.05$) 12 months after surgery, and statistically significant improvements in QoL's sustainability after 12 months (one study).
Procedure-related adverse events (n=3) occurred, where prostheses extruded during surgery, and anal discomfort/pain was felt (n=11). Device-related adverse events, i.e., prostheses' dislodgement (n=31) and removed/extruded prostheses (n=3), occurred. Studies were judged with moderate/high RoB. The strength of evidence for safety was judged to be very low.
Conclusions. Implantable bulking agents might be an effective and safe minimally invasive option in FI treatment if conservative therapies fail. FI severity significantly improved, but not QoL, which needs to be explored in further studies. Due to the uncontrolled nature of the case series, comparative studies need to be awaited.

OP19 Comparative Effectiveness Of Common Treatment Options For Benign Prostatic Hyperplasia: A Systematic Review And Network Meta-Analysis

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Introduction. Treatment options for men with moderate-to-severe lower urinary tract symptoms due to benign prostatic hyperplasia (BPH) include medical therapy, minimally invasive surgical therapies (MISTs), and invasive surgical procedures. While these treatments are recommended by American Urological Association Guidelines,

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they have different clinical profiles impacting both efficacy and durability outcomes. Using an indirect comparison approach, this study assessed the clinical effects of combination therapy (CT) using alpha-blockers and 5-alpha reductase inhibitors, two emerging MISTs (prostatic urethral lift [PUL] and water vapor thermal therapy [WVTT]), and two invasive surgical procedures (photoselective vaporization of the prostate [PVP] and transurethral resection of the prostate [TURP]).

Methods. A systematic search of Medline, Embase, Cochrane Library, and relevant health technology assessment (HTA) databases was conducted to identify randomized and non-randomized clinical trials of the five treatments published prior to December 2020. Trials were included if they reported changes in International Prostate Symptom Score (IPSS) and retreatment rates, without any country or language restrictions. A random-effects network meta-analysis (NMA) with an aggregate regression model was performed to account for the baseline BPH severity and characteristic differences among men from the different trials.

Results. A total of 237 of 3,104 retrieved abstracts were included for full-text review. Of these, 16 randomized and four non-randomized clinical trials were included in the NMA. The random-effects NMA showed among medical and minimally invasive therapies, WVTT had the greatest one-year IPSS improvement (-Δ11.7), followed by PUL (-Δ10.4) and CT (-Δ10.3). The one-year IPSS improvement for TURP and PVP was comparable (-Δ14.1 vs. -Δ13.8, respectively; p-value=0.675). The one-year retreatment rates were lowest for WVTT (3.0%), followed by CT (3.6%), TURP (6.3%), PVP (7.8%), and PUL (8.0%).

Conclusions. WVTT provided greater clinical and durability benefits compared to other less invasive treatment options for men with BPH. Given NMA is increasingly used in HTA processes, this study provided systematically synthesized evidence that could facilitate decision-makers in determining new technology coverage decisions globally.

OP20 Is The Quality Of Evidence In Health Technology Assessment Deteriorating Over Time?: A Case Study On Cancer Drugs In Australia

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Introduction. Recently, there have been concerns regarding a trend toward poorer quality evidence being accepted by regulatory institutions and the consequent impact on health technology assessment (HTA) decision-making. This study aimed to determine whether there has been a change in the quality of evidence provided on cancer drugs proposed for listing on the Pharmaceutical Benefits Scheme, using data solely extracted from public summary documents (PSD) published by the Australian government.

Methods. PSDs published from July 2005–2020 were reviewed. Metrics associated with quality of evidence were extracted, including the directness of comparison, study design, sample size, and risk of bias (RoB). Additional data were extracted to provide greater context to any observed trends in quality of evidence. Analyses were performed across different time periods. Associations between the quality of evidence and time periods were explored using logistic regression analysis.

Results. In total, 214 PSDs were included in the analysis. Only 13 percent of submissions provided a single arm study or observational study as the key evidence; however, 37 percent of submissions did not contain a direct ('head-to-head') comparison relevant to Pharmaceutical Benefits Advisory Committee (PBAC) decision-making. Among all submissions containing direct evidence, about half had findings of a moderate/high/unclear RoB. Among all submissions containing indirect comparisons, over half had transitivity issues. In submissions containing direct comparisons, there was an increase in the RoB over time even after adjusting for trial data maturity and the rareness of the drug indication (odds ratio [OR] 1.30; 95% confidence interval [CI] 0.99, 1.70). There were no clear time trends observed in sample size, directness, study design, or transitivity issues during any of the observed time periods.

Conclusions. In the last 7 years, a high proportion of cancer drug submissions presented findings with a high RoB and transitivity issues. As the evidence dossiers provided to the PBAC are often congruent with submissions made elsewhere, this poor evidence quality is of concern and can only lead to higher levels of decision-maker uncertainty.

OP21 A Critical Review Of Existing Health Inequality And Health Inequity Frameworks In Evidence Synthesis

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Introduction. In recent years, there has been a growing recognition that health equity and health inequalities should be a consideration in all aspects of research. Since the Commission on Social Determinants of Health by the World Health Organization was established in 2005, there has been a growing interest in tackling systemic differences in health outcomes, including expanding the scope to health research including evidence synthesis and health technology assessments (HTA). This analysis aims to identify health inequality and health inequity frameworks that exist to help structure and plan research methods in evidence synthesis.

Methods. A critical analysis of the existing frameworks used in evidence synthesis to address health inequality and/or inequity was undertaken. Comprehensive, systematic searching of seven social science electronic databases and grey literature was undertaken based on the Behavior/phenomenon of interest, Health context and Model/Theory (BeHEMoTh) model, from 1990 to May 2022 to identify all relevant studies. A narrative synthesis approach was used to critically appraise the existing frameworks.

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