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BUDGET IMPACT MODEL OF SAME-DAY-DISCHARGE COMPARED TO INPATIENT BARIATRIC SURGERY IN UK, SPAIN, AND THE NETHERLANDS

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Objectives: Several studies have shown that same-day-discharge (SDD) bariatric surgery can be performed as safe as inpatient surgery. The objective of this study is to compare the impact on economic outcomes and capacity of conducting SDD bariatric procedures versus inpatient surgery in the UK, Spain and the Netherlands considering each country's unique reimbursement system. In the UK, bariatric surgery is reimbursed through a single national tariff, regardless of the setting. In the Netherlands, there are separate national tariffs for SDD and for inpatient setting; in Spain, hospitals are funded through a global budget. Methods: A model was developed to assess cost and capacity from the hospital's perspective. Costs were calculated based on local length of stay (LoS) data for inpatient setting and a conservative assumption of 1-day LoS for SDD. The cost of one additional phone call for SDD as per a protocol conducted in a Dutch hospital was also included. It was assumed all other variables such as operating room (OR) time were unchanged. Capacity was assessed based on the different LoS between settings having a constant number of available beds. Results: In the UK and Spain, SDD could lead to savings of £285 and €578 per procedure, respectively. In the Netherlands, the reduction in LoS was associated with savings of €618 for SDD. However, the hospital received €740 lower revenue due to the difference in national tariff for each setting. However, as SDD reduces the LoS by half (1 vs 2 days), this translates into an increase in bed capacity that could lead to higher surgery volumes. Conclusions: The results show that SDD bariatric surgery may be a cost-saving procedure compared to inpatient surgery from the hospital perspective in the UK and Spain. In all three countries, SDD lead to the increase in capacity due to the reduction in LoS.

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USE OF EARLY FEASIBILITY STUDIES TO INFORM DEVELOPMENT OF MEDICAL DEVICES

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Objectives: Medical device development often involves iterative design modifications during pre-clinical and early clinical evaluations. Early Feasibility Studies (EFS) are limited clinical investigations, aimed at evaluating design concepts concerning initial clinical safety and functionality, potentially informing design modifications. These studies are the focus of a dedicated FDA program in the US and classified under EN ISO14155:2020 in Europe. Despite their importance, no public registries exist of EFS and there is limited evidence on their recent use and impact. This study aimed to identify and describe EFS conducted for medical devices globally. Methods: We extracted information from several public clinical study registries and previous systematic literature reviews. We included all studies defined as EFS as well as all interventional, open-label studies with a sample size <30 patients (EFS-like). For each study, data collected included sample size, therapeutic area, primary and secondary outcomes, sponsors and investigating centers, study status, and related publications. Information was retrieved from the registries using a web scraping algorithm when needed. Data was analyzed using descriptive statistics. Results: Overall, the dataset comprises 559 EFS and EFS-like studies, predominantly located in the United States (about 45% of the sample), followed by European countries (28%). Nearly half of the studies focus on circulatory system diseases, while around 10% of them remain incomplete (suspended, terminated, withdrawn or withheld). Notably, the number of conducted studies has shown a stable increasing trend in recent years, both in Europe and in the US. Conclusions: EFS studies have been increasingly used during medical device development in the US and Europe. However, their impact on approval time, and post-market safety and efficacy profiles is still unclear. Reporting standards for EFS in publicly available registries would improve transparency and facilitate research on their role for device development.

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MEEK MICROGRAFTING IN THE GERMAN HOSPITAL SETTING: AN ASSESSMENT OF RECENT DEVELOPMENTS IN WOUND MANAGEMENT



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Objectives: It is estimated that approximately 3,500 per 1 million people are living with a wound, of which 525 per 1 million people suffer from a chronic wound, which lasts at least 1 year. The standard of care for wound coverage is to use an autologous skin graft, but large and or chronic wounds pose a challenging problem. Innovative developments in micrografting technologies such as autologous micrografting for wound coverage. **Methods:** This retrospective data analysis was based on German hospital data from the Institute for the Hospital Remuneration System (InEK) of the years 2019-2023. Meek micrografting procedures were identified by operation and



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procedure key (OPS) code 5-925.7*. Localizations of treatment were identified by OPS 6-digit codes. **Results:** Between 2019-2023 n=647 hospitalized patients received at least one Meek micrografting procedure. Of these, 41% patients were 60+ years old and 65% were male. Noteworthy, 2.5% of patients were <10 years and 3.9% were <16 years young. The number of patients receiving such procedure increased 2,7-times from 2019 (n=69) to 2023 (n=185). Most treated localizations with Meek micrografting were thighs and knees (13.1%), followed by upper arm and elbow (11.4%) and lower leg (11.2%). Least treated localization was hairy scalp (0.3%). On average, patients received 1.2 applications of meek micrografting during their hospitalization. Weighted average length of stay was 44.7 days (2019-2023). Arithmetic mean length of stay decreased by 8.8 (95%CI: -0.4, 18.0) days from 49.7 (\pm 31.8) days in 2019 to 40.9 (\pm 36.5) days in 2023. **Conclusions:** Autologous micrografting may provide the starting signal for faster endogenous wound healing response. The increased usage of meek micrografting procedures in the inpatient setting in Germany might prompt the implementation of innovate technologies in wound management.

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ARTIFICIAL INTELLIGENCE-BASED TOOLS DESIGNED TO PREDICT FUTURE MECHANICAL VENTILATION AND/OR MORTALITY IN HOSPITALISED COVID-19 PATIENTS: A SYSTEMATIC LITERATURE REVIEW



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Objectives: Artificial intelligence (AI) can be used to create personalised predictions for mortality and mechanical ventilation (MV) in patients hospitalised with COVID19. Such tools may offer valuable early warning alerts and spur prompt intervention to prevent poor outcomes. However, it is important to proactively test to ensure that these tools work fairly and equally well in all populations in which they are intended to be applied. This systematic literature review covers AI-based tools that are designed to predict mortality and/or MV in patients hospitalised with COVID19. Methods: This study searched articles from PubMed, MEDLINE and EMBASE. This study was performed using the AutoLit platform (Nested Knowledge). Papers had to be published between 01-Jan-2020 to 10-Jan-2024. Results: Originally 181 studies were identified, with 140 papers remaining after two human and one Nested Knowledge AI-powered screening. Most models focussed on mortality (87.1%), 6.4% on MV and 6.4% on both outcomes. Datasets were global, including from North America (30.7%) and Europe (21.4%). Where reported, average dataset size was 6589.7 individuals, 58.5% male, and average age of 60.2 years. Where reported, the average predictive accuracy was 87.3%. Most papers used tree-based methods (63.6%) and/or deep learning (29.3%). Most algorithms (91.4%) used demographic features and lab test data (81.4%), and some used vital signs (39.3%). Less than one-third of studies included external validation (27.3%). Most studies did not report ethnicity (78.6%) and only one explicitly reported an assessment of ethnicity bias. Conclusions: These tools exhibit good predictive abilities and they may be able to meaningfully improve patient care and outcomes. However, accuracy is not the only dimension in which to understand AI tool performance. The presence of un-representative training data, lack of external validation data and reported bias assessments indicate significant room for improvement. These tools should work well for all patients whose care they are intended to inform/improve.

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UTILIZING SINGLE-USE RHINOLARYNGOSCOPES FOR FEES: A PRE-/POST-ADOPTION CAPABILITY ASSESSMENT McWilliams L,¹ Cool C,² Haislip I³



Objectives: In other endoscopy specialties, single-use (SU) scopes have shown to save significant time per procedure by eliminating reprocessing and repairs, enabling physicians to see more patients. For hospital-based speech rehabilitation departments, flexible endoscopic evaluation of swallowing (FEES) exams can be ordered on short notice, meaning the equipment needs to be mobile and readily accesible. Availability concerns with reusable (RU) rhinolaryngoscopes may impede the timing and overall quality of patient care. This study aimed to evaluate procedural volume implications pre- and post-adoption of SU rhinolaryngoscopes in a hybrid model for FEES. Methods: In December of 2022, a large community-based hospital adopted a hybrid use of the SU Ambu aScope 4 RhinoLaryngo and Olympus RU rhinolaryngoscopes. Retrospective analysis of FEES volumes were calculated as well as RU repairs. Results: 1,709 FEES exams were completed in 2022 with RU rhinolaryngoscopes, amounting to 142.4 exams per month. During this timeframe, the RU scopes experienced frequent repairs with at least 1 RU scope down for 93 days in 2023. Additionally, an SLP was on maternity leave for three months, reducing the number of available endoscopists. Despite the number of RU scope repairs and reduced employee support, the hospital maintained the same FEES caseload with the hybrid SU system compared to the previous year, with 1,738 FEES exams completed in 2023, amounting to 144.8 exams per month. Conclusions: Incorporating SU rhinolaryngoscopes alleviated scope availability and workflow issues, as the same volume of FEES exams were performed with the SU hybrid system despite RU scope repairs and staff leave. Additionally, SU scopes mitigated issues related to sterile processing staff turnover and labor shortages, which tends to delay RU rhinolaryngoscope turnaround. Lastly, the introduction of SU scopes enabled expansion of FEES competency training courses, enabling more SLPs to perform FEES when necessary.