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Enhancing Surgical Efficiency and Promoting Local Innovation: An Observational Study of the Icompbag Positioning Device and its Socioeconomic Implications

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ABSTRACT

Effective patient positioning for head, neck, and maxillofacial surgery is crucial but often challenging with standard imported devices like gel pads, which incur high costs with approximately RM4000 per unit, require multiple personnel for placement post-anaesthesia, hence risking complications like ETT dislodgement, and impede workflow. This study evaluates the IComPBag, an innovative, locally developed inflatable positioning device designed to address these clinical and socioeconomic challenges. We aimed to compare the efficiency, safety, and cost-effectiveness of the IComPBag versus standard gel pads for surgical patient positioning. We conducted a prospective observation study at the Tuanku Mizan Armed Forces Hospital, enrolling 60 patients undergoing relevant elective surgeries, with two temporal cohorts, the standard Gel Pad group (n = 30), placed post-induction via manual lift and the IComPBag group (n = 30), placed pre-induction and inflated by one operator post-intubation. Primary outcomes were positioning time and the number of staff required. Baseline characteristics were comparable between groups. Positioning time was significantly shorter in the IComPBag group compared to the Gel Pad group (mean 125.2 sec. ± 35.5 sec. vs. 261.8 sec. ± 45.2 sec., respectively; $P < 0.001$), and significantly fewer staff were needed (83.3% requiring one operator vs. 23.3%; $P < 0.001$). The IComPBag offered a more than 96% cost reduction, and no adverse events related to positioning occurred in either group. We conclude that the locally developed IComPBag significantly improves surgical positioning efficiency, reduces staffing requirements, and offers substantial cost savings compared to standard imported gel pads while maintaining patient safety. Our findings highlight the value of clinician-led, needs-driven local innovation in enhancing healthcare delivery, promoting economic resilience, and improving patient and societal well-being within Malaysia and potentially similar settings.

Keywords: Surgical Efficiency, Observational Study, Socioeconomic Implications, Optimal Patient

Introduction

Optimal patient positioning is crucial for ensuring safety and effectiveness in surgical procedures, particularly in specialities such as head and neck, thyroid, and maxillofacial surgery, where precise access to the surgical field is essential. To achieve this necessary exposure, specialised positioning aids are often required. However, commonly used standard devices, like silicone gel pads, present significant logistical, economic, and clinical challenges that impact the immediate operating room environment and highlight broader socioeconomic concerns related to reliance on healthcare technology [1].

The traditional practice of repositioning patients after anaesthesia induction occurs during a critical period of vulnerability. This phase requires meticulous attention to avoid potentially severe

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complications, with endotracheal tube (ETT) dislodgement being a primary concern. Standard protocols typically need three or more personnel for repositioning, which increases operating room time and drains valuable resources [2].

The IComPBag was conceived and developed to address these multifaceted issues in Malaysia through a collaborative effort involving healthcare professionals from diverse academic backgrounds and the Department of Anaesthesia, Tuanku Mizan Armed Forces Hospital, Kuala Lumpur. This innovative device is a locally manufactured, portable, and inflatable system designed for optimal patient positioning across various surgical disciplines, including maxillofacial surgery, otorhinolaryngology-head and neck, orthopaedics, endocrinology, and obstetrics [3].

The IComPBag (Figure 1) system consists of several key components: a primary inflatable bag, an elongated connecting tube, a handheld manual pump, an auxiliary puncture tube for alternative inflation and deflation, a safety clamp to prevent inadvertent air leakage, and an adjusting screw that serves as a valve to control the air pressure within the bag precisely.

Figure 1: The IComPBag Inflatable Patient Positioning Device

Constructed from Renolit Solmed Meditub, a medical-grade material used in critical blood-contact devices, the IComPBag is engineered for the safety of both patients and healthcare workers. Its gas-impervious and non-blocking (non-stick) properties facilitate easy inflation and storage, while its non-kinking features and excellent transparency enhance usability. The material is suitable for steam, Ethylene Oxide (ETO), and gamma sterilisation methods, thereby minimising the risk of skin irritation and infection for patients. The soft, flexible nature of the material ensures even pressure distribution from the patient's body, reducing the risk of developing pressure points.

The rectangular inflatable bag has double-sealed short edges and strategically placed extra compression points, allowing it to withstand high pressure from the patient's body weight. Curved angles inside the bag promote even internal pressure distribution. A 750mm circular connecting tube delivers air from the handheld pump to the bag, maintaining an optimal distance between the operator and patient during inflation. This flexible, oval-shaped handheld pump is designed for repeated manual compression to inflate the device.

The application protocol for the IComPBag is designed to enhance efficiency and safety. The device is placed under the patient's shoulders while awake and supine on the operating table. After the induction of anaesthesia and successful endotracheal intubation, a single operator inflates the IComPBag by repeatedly squeezing the handheld pump. Once the desired level of inflation and patient positioning is achieved, the operator secures the adjusting screw, preventing any air escape and maintaining stable positioning throughout the surgical procedure. This streamlined, single-operator approach to patient positioning following induction is a core aspect of the IComPBag's design philosophy.

Problem Statement

Effective patient positioning during surgery is crucial, yet standard methods face significant clinical and socioeconomic challenges, particularly after anaesthesia induction, when patients are most vulnerable. Manual repositioning requires extreme care to avoid complications such as endotracheal tube (ETT) dislodgement and typically involves three or more personnel. This process consumes valuable operating room time and resources. The inherent inefficiency and risks associated with conventional positioning techniques represent a primary clinical problem addressed by this research.

Additionally, there is a significant economic and systemic issue due to the heavy reliance on imported positioning devices, such as standard silicone gel pads. The approximately RM4000 per unit cost of these expensive devices contributes considerably to healthcare expenditures. This dependence makes national healthcare systems, especially in developing and middle-income countries like Malaysia, vulnerable to fluctuations in the global economy, supply chain disruptions, and the impact of trade policies such as tariffs, issues that were particularly highlighted during the COVID-19 pandemic.

Despite having significant domestic manufacturing capabilities in certain medical product areas, such as gloves and catheters, Malaysia imports approximately 95% of its required medical devices. This high level of import dependency represents both a critical economic vulnerability and a missed opportunity for fostering local innovation and manufacturing. Furthermore, standard gel pads have limitations, including their radiopaque nature, which can hinder intraoperative imaging and the logistical burden of stocking multiple sizes.

Objectives

This study aimed to primarily compare the effectiveness of the IComPBag positioning device with standard gel pads by evaluating the average time required to achieve optimal surgical positioning for elective surgeries involving the head, neck,

ENT, or dental-maxillofacial regions. Additionally, the study sought to determine the number of personnel needed for surgical positioning when using the IComPBag compared to standard gel pads. Further objectives included evaluating and comparing the direct costs associated with using the IComPBag versus imported gel pads and assessing and comparing the incidence of positioning-related complications, such as endotracheal tube (ETT) dislodgement, device malfunction, and skin adverse events, between the two groups.

Methodology

This prospective observational study was conducted in the Department of Anaesthesia and Intensive Care at Tuanku Mizan Armed Forces Hospital in Kuala Lumpur, Malaysia, from May 1, 2016, to April 30, 2024. Sixty patients scheduled for elective surgeries involving the head and neck, Ear-Nose-Throat (ENT), or dental-maxillofacial areas that required specific positioning were enrolled after providing informed consent. The inclusion criteria specified that patients should have an American Society of Anaesthesiologists (ASA) physical status of I or II, be aged between 18 and 70 years, and weigh between 50 and 90 kilograms. The cohort was divided into two temporal groups: the Gel Pad group (48 months, from May 1, 2016, to April 30, 2020) and the IComPBag group (48 months, from May 1, 2020, to April 30, 2024). Due to the nature of the interventions, blinding the personnel who performed the positioning was not feasible.

All participants received a standardized anaesthetic regimen and standard ASA monitoring throughout the procedure. This monitoring included a 3-lead electrocardiogram, non-invasive blood pressure measurement, pulse oximetry, end-tidal capnography, oxygen and anaesthetic gas analysis, and temperature monitoring. Anaesthesia was induced intravenously with fentanyl (2 mcg/kg), propofol (2 mg/kg), and rocuronium (0.6 mg/kg) to facilitate endotracheal intubation. Maintenance of anaesthesia was achieved with sevoflurane in a mixture of oxygen and air, targeting a minimum alveolar concentration (MAC) of 1.3.

Patients in the Gel Pad group were positioned after induction, following standard institutional practices, which involved the manual lifting by the theatre team to correctly place the gel pad. In contrast, patients in the IComPBag group had the deflated device positioned under their shoulders before induction. To ensure compliance with the procedure, anaesthesia personnel using the IComPBag received specific training, which included both theoretical instruction and hands-on practice for device placement and inflation. One anesthesiologist (MFL) was designated to position the patients with the IComPBag. After confirming the correct placement of the endotracheal tube, a designated operator inflated the IComPBag to achieve the desired surgical position.

After the surgical procedure, intravenous neostigmine (0.05 mg/kg) and atropine (0.02 mg/kg) were administered to reverse neuromuscular blockade. Following extubation, all patients were transferred to the post-anaesthesia care unit (PACU) for monitoring for a minimum of 30 minutes before being discharged to the surgical ward.

The primary outcome measured was the positioning time, recorded in seconds using a stopwatch from the start of the positioning manoeuvre until the surgeon confirmed the desired position. Secondary outcomes included the number of staff members actively involved in positioning, patient demographics, and an economic impact assessment comparing the unit costs of the devices. Additionally, potential complications related to the positioning manoeuvre or device usage, such as endotracheal tube dislodgement, device malfunction, skin marks, allergic reactions, or pressure effects, were systematically monitored and documented for all patients throughout the perioperative period as a key safety outcome. Data analysis was performed using SPSS Statistics version 26 (IBM Corp., Armonk, NY, USA). Continuous variables were compared between groups using the Independent Samples t-test after assessing normality. Chi-square or Fisher's Exact tests were used for categorical variables. Statistical significance was established at a P-value of less than 0.05.

Results

The baseline characteristics of the participants and the key outcomes of the study are summarised in Table 1. Our analysis confirmed that the two study groups were comparable at baseline. There were no statistically significant differences between the IComPBag group and the Gel Pad group regarding mean body weight (79.4 kg ± 12.1 kg vs. 76.5 kg ± 11.8 kg; $P = 0.354$) or mean age (48.2 years ± 14.5 years vs. 50.1 years ± 15.2 years; $P = 0.612$). The distribution of ASA physical status was also similar between the groups ($P = 0.648$).

Regarding the primary outcome, we found a statistically significant difference in positioning time between the two methods. The mean time required to achieve the final surgical position was substantially shorter for the IComPBag group, averaging 125.2 seconds (± 35.5 seconds), compared to 261.8 seconds (± 45.2 seconds) for the Gel Pad group ($P < 0.001$).

Furthermore, manpower requirements for positioning were significantly reduced by using the IComPBag ($P < 0.001$). In the IComPBag group, 83.3% (25 out of 30) of the patients were successfully positioned by a single staff member. In contrast, only 23.3% (7 out of 30) of the patients in the Gel Pad group could be positioned by one person, while the remaining 76.7% (23 out of 30) required assistance from multiple team members.

In terms of economic impact, the IComPBag demonstrated a clear advantage. As a locally developed and manufactured device, its approximate unit cost is RM150, representing a 96.25% cost reduction compared to the estimated RM4,000 cost of an imported standard silicone gel pad.

Importantly, no adverse events or complications related to the positioning manoeuvres or devices were reported in either group throughout the study period. This included monitoring for and finding no instances of endotracheal tube dislodgement, device malfunctions, skin marks, allergic reactions, skin irritation, or pressure points. These findings collectively demonstrate the clinical effectiveness of the IComPBag, its potential to reduce healthcare costs significantly, and its ability to optimise resource allocation, highlighting how local innovation can effectively address both clinical and economic challenges.

Table 1: Baseline Characteristics and Key Outcomes Comparing IComPBag with Standard Gel Pad.

Characteristic		IComPBag Group (n = 30)	Gel Pad Group (n = 30)	P value[a]
Baseline characteristics	Mean Age (years ± SD)	48.2 ± 14.5	50.1 ± 15.2	0.612
	Mean Weight (kilogram ± SD)	79.4 ± 12.1	76.5 ± 11.8	0.354
	ASA Physical Status, n (%)			
	ASA[b] I	19 (63.3%)	17 (56.7%)	0.648
	ASA[b] II	11 (36.7%)	13 (43.3%)	
Primary Outcome	Mean Positioning Time (sec. ± SD)	125.2 ± 35.5	261.8 ± 45.2	< 0.001
Secondary Outcome	Staff Required for Positioning, n (%)			
	One Person	25 (83.3%)	7 (23.3%)	< 0.001
	> One Person	5 (16.7%)	23 (76.7%)	
Economic Comparison	Approximate Unit Cost (RM[c])	150	4000	NA[d]
Adverse Events	ETT dislodgement	0	0	NA[d]
	Device malfunctions	0	0	NA[d]
	Skin marks	0	0	NA[d]
	Allergic reaction or skin irritation	0	0	NA[d]
	Pressure points	0	0	NA[d]

Values are presented as mean ± standard deviation (SD) or number (n) and percentage (%).
[a]P-values calculated using Independent Samples t-test for continuous variables and Chi-square test for categorical variables. Statistical significance set at $P < 0.05$.
[b]ASA: American Society of Anaesthesiologists physical status classification system.
[c]RM: Malaysian Ringgit.
[d]N/A: Not Applicable (statistical comparison not performed for cost or adverse events in this context).

Discussion

Our observational study provides compelling evidence that the locally developed IComPBag offers significant advantages over traditional gel pads for surgical patient positioning in head, neck, and maxillofacial procedures. We observed a marked reduction in mean positioning time with the IComPBag (125.2 seconds vs. 261.8 seconds, $P < 0.001$), which translates directly to improved operating theatre efficiency. This improvement could enable better scheduling and throughput for surgical lists. Furthermore, the drastic decrease in personnel required for positioning with the IComPBag (83.3% positioned by one person vs. 23.3% for gel pads, $P < 0.001$) optimises resource allocation by freeing valuable staff members to focus on other critical tasks within the theatre.

Beyond these efficiency gains, our findings suggest that the IComPBag method inherently enhances patient safety. By minimising the need for manual lifting and manipulation of the patient after intubation, the risk of complications, such as endotracheal tube dislodgement, a primary anaesthetic concern, is substantially reduced. Although no adverse events occurred in either group during our study, the reduced handling required for the IComPBag is a procedural safeguard compared to the multi-person lift often necessary for gel pad placement.

Our study also reveals advantages that extend beyond clinical efficacy into the socioeconomic realm. The economic implications are profound; the IComPBag's significantly lower unit cost, compared to approximately RM4000 for imported pads, presents potential for substantial cost savings for healthcare institutions. These savings could be redirected to address other critical healthcare priorities. More fundamentally, the success of the IComPBag exemplifies how local medical innovation can address vulnerabilities related to dependency on imported medical technologies. By developing regional capacity for innovation and manufacturing, as demonstrated here, we build resilience against external economic shocks, such as currency fluctuations, supply chain disruptions, and tariffs, factors that became particularly critical during the recent global COVID-19 pandemic. This approach strengthens national economic resilience and promotes greater self-sufficiency in the vital healthcare sector.

The case of the IComPBag illustrates that impactful innovation does not always require high-tech, capital-intensive solutions. Simple yet elegant solutions that address everyday clinical challenges can significantly benefit healthcare systems and societies. This principle of "appropriate technology," which focuses on developing contextually relevant, affordable, and sustainable solutions, holds particular value for healthcare systems in developing and middle-income countries, such as Malaysia.

Furthermore, the development journey of the IComPBag underscores the vital role those academic institutions can play in driving medical innovation. Universities represent a unique convergence of clinical expertise and research infrastructure. However, translating clinical insights into practical innovations

requires deliberately creating supportive ecosystems. Key strategies include dedicated innovation funding, accessible intellectual property support such as Technology Transfer Offices, fostering interdisciplinary collaboration (connecting medicine with engineering, business, and design), building industry partnerships for development and commercialisation as seen in Malaysian universities, recognising innovation in academic progression criteria, allocating protected innovation time for clinicians, and offering tailored innovation skills development, such as design thinking, prototyping, and entrepreneurship. By fostering such environments, universities can empower clinician-innovators to develop locally relevant, affordable, and effective medical technologies that benefit patients and society.

Developing local medical innovation capabilities also significantly contributes to national economic resilience. This aligns with strategic national goals such as Malaysia's New Industrial Master Plan 2030, which prioritises advancing capabilities in product design, development, and integrated services within the medical device sector. Given the projected growth of Malaysia's domestic medical device market, expected to reach US$4.5 billion by 2028, there is a strategic opportunity to transition from being primarily an importer to becoming a developer and manufacturer of innovative medical technologies. Such a shift would reduce economic vulnerability, create high-value jobs, cultivate local expertise, and potentially establish Malaysia as a regional hub for medical innovation. Industry organisations like the Malaysian Medical Device Manufacturers Association (PERANTIM) are crucial in strengthening this ecosystem.

We acknowledge several limitations in our study. Its single-centre design may limit the generalizability of our findings to other institutions with potentially different staffing models or patient populations. Additionally, the non-blinded nature of the intervention could introduce a risk of performance bias. However, we believe the objective nature of the primary outcome (positioning time) mitigates this concern to some extent. Future research should ideally include multi-centre trials to validate these findings across diverse settings. A formal cost-benefit analysis incorporating indirect savings, such as reduced theatre time and potential complication avoidance, would further strengthen the economic argument. Exploring the utility of the IComPBag in other surgical specialities requiring similar patient positioning would also be beneficial.

Conclusion

In conclusion, our findings demonstrate that the IComPBag device presents significant advantages for surgical patient positioning compared to standard imported gel pads. We established that the IComPBag is faster to implement and requires fewer personnel, resulting in substantial improvements in operating theatre efficiency. Furthermore, its markedly lower cost offers considerable economic benefits. The inherent design of the IComPBag, which minimises patient handling during the critical post-intubation phase, also promotes enhanced patient safety.

As a locally developed and manufactured medical device originating from Malaysia, the IComPBag exemplifies the tangible benefits achievable through indigenous innovation. It directly addresses clinical efficiency challenges while reducing healthcare costs and lessening dependence on imported technologies. Our study highlights how clinician-led, university-supported innovation can effectively bridge the gap between clinical needs and broader societal goals, contributing to national economic resilience and healthcare sustainability.

The success of the IComPBag offers valuable lessons for healthcare systems, academic institutions, and policymakers regarding the strategic importance of investing in and fostering local medical innovation ecosystems. Creating supportive environments can empower healthcare professionals to develop contextually appropriate solutions that serve specific clinical needs while building greater national self-sufficiency. This approach aligns with national aspirations for an innovation-driven economy, advancing both healthcare outcomes and economic development goals concurrently. Ultimately, the IComPBag represents a user-friendly, portable, safe, and economically viable positioning alternative, suitable for widespread adoption across various healthcare facility levels, offering positive contributions to patient care and the healthcare economy.

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