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Outcomes After Inguinal Hernia Repair With Mesh Performed by Medical Doctors and Surgeons in Ghana

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IMPORTANCE Inguinal hernia is the most common general surgical condition in the world. Although task sharing of surgical care with nonsurgeons represents one method to increase access to essential surgery, the safety and outcomes of this strategy are not well described for hernia repair.

OBJECTIVE To compare outcomes after inguinal hernia repair with mesh performed by medical doctors and surgeons in Ghana.

DESIGN, SETTING, AND PARTICIPANTS This prospective cohort study was conducted from February 15, 2017, to September 17, 2018, at the Volta Regional Hospital in Ho, Ghana. Following successful completion of a training course, 3 medical doctors and 2 surgeons performed inguinal hernia repair with mesh according to the Lichtenstein technique on 242 men with primary, reducible inguinal hernia.

MAIN OUTCOMES AND MEASURES The primary end point was hernia recurrence at 1 year. The noninferiority limit was set at 5 percentage points. Secondary end points included postoperative complications at 2 weeks and patient satisfaction, pain, and self-assessed health status at 1 year.

RESULTS Two-hundred forty-two patients were included; 119 men underwent operations performed by medical doctors and 123 men underwent operations performed by surgeons. Preoperative patient characteristics were similar in both groups. Two-hundred thirty-seven patients (97.9%) were seen at follow-up at 2 weeks, and 223 patients (92.1%) were seen at follow-up at 1 year. The absolute difference in recurrence rate between the medical doctor group (1 [0.9%]) and the surgeon group (3 [2.8%]) was −1.9 (1-tailed 95% CI, −4.8; $P < .001$), demonstrating noninferiority of the medical doctors. There were no statistically significant differences in postoperative complications (34 [29.1%] vs 29 [24.2%]), patient satisfaction (112 [98.2%] vs 108 [99.1%]), severe chronic pain (1 [0.9%] vs 4 [3.7%]), or self-assessed health (85.9 vs 83.7 of 100) for medical doctors and surgeons.

CONCLUSIONS AND RELEVANCE This study shows that medical doctors can be trained to perform elective inguinal hernia repair with mesh in men with good results and high patient satisfaction in a low-resource setting. This finding supports surgical task sharing to combat the global burden of hernia disease.

Invited Commentary

Supplemental content

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Inguinal hernia is a common surgical condition, with an estimated 220 million cases worldwide.[1] Population-based studies from sub-Saharan Africa demonstrate a prevalence of inguinal hernia in men ranging between 7% and 13%.[2-4] Each year, 20 million inguinal hernia surgeries are performed, making hernia repair the most commonly performed general surgical procedure globally.[5-7] However, the rate of hernia surgery remains low in sub-Saharan Africa where the need is greatest.[1,8,9] This low rate leads to morbidity, mortality, and negative economic consequences.[1,10] It has been estimated that an additional 1 million inguinal hernias in need of surgical repair will develop by 2022 in Ghana.[11] Capacity for essential surgical care, such as hernia repair, must be increased to meet this need and combat death and disability associated with surgical disease in low-resource settings.

Safe provision of essential surgery requires a functioning health care system, trained workforce, and adequate infrastructure.[12] Because of limited surgeon supply, major surgery is not always performed by specialist surgeons in sub-Saharan Africa.[13,14] Task sharing of surgical procedures with nonsurgeons is practiced in many African countries to various extents, depending on national policies.[13,14] In Ghana, most inguinal hernia repairs are performed by medical officers, who are doctors with no formal training in surgery or any other specialized field.[15] Previous studies have demonstrated that nonphysician clinicians can perform surgical procedures, including cesarean section and laparotomy, with similar results compared with surgical specialists.[16-19] However, the safety and effectiveness of task sharing of surgical care with doctors without specific surgical training is not well described. For clarity, medical officers are referred to as medical doctors in this article.

In addition to insufficient rates of inguinal hernia surgery, access to modern methods of repair is limited in sub-Saharan Africa.[1,9] The standard for open hernia surgery is the anterior mesh repair according to the Lichtenstein technique.[20,21] This method results in significantly lower rates of hernia recurrence compared with tissue repair techniques that remain common in sub-Saharan Africa today.[20] It has been demonstrated that mesh repair under local anesthesia is safe and effective in sub-Saharan Africa; however, cost and limited training in this technique preclude routine practice of mesh repair in this part of the world.[22] To most effectively address the burden of inguinal hernia disease, a workforce of sufficient size that is well trained in the Lichtenstein technique is needed.

The aim of the present prospective cohort study was to compare the outcomes after mesh inguinal hernia repair under local anesthesia performed by medical doctors and surgeons in Ghana. We hypothesized that the medical doctors would be noninferior to surgeons in terms of recurrence, postoperative complications, chronic pain, and patient satisfaction after inguinal hernia repair with mesh.

Key Points

Question What are the outcomes after mesh inguinal hernia repair performed by medical doctors compared with surgeons in Ghana?

Findings In this cohort study of 242 men with primary reducible inguinal hernia, there was no significant difference in hernia recurrence at 1 year after inguinal hernia repair with mesh performed by medical doctors compared with surgeons (0.9% vs 2.8%).

Meaning This study shows that medical doctors can be trained to perform inguinal hernia repair with mesh in men with good results in a low-resource setting and supports surgical task sharing to combat the global burden of hernia disease.

Methods

Study Design

This was a prospective cohort study with noninferiority design. The study was conducted from February 15, 2017, to September 17, 2018. Ethical approval was obtained from the Ghana Health Service Ethical Review Committee and the University of Pennsylvania Institutional Review Board. Patients were enrolled in the study after giving written informed consent. The patients' transportation costs to follow-up visits were compensated.

Surgical Training, Technique, and Material

Consultant general surgeons (3 from Ghana [M.O.-Y., S.T., and F.A.A.] and 1 from the United States [J.H.B.] serving as the trainers) provided the training for the 3 medical doctors and 2 general surgeons participating in the program (the trainees) in tension-free mesh hernia repair according to the Lichtenstein technique.[23] The medical doctors had completed medical school followed by a 2-year general internship but had no formal training in surgery. The surgeons had completed 6 years of postgraduate training in general surgery. Only trainees currently performing open-tissue inguinal hernia repair were trained.

The trainees attended a 2-week course created and led by the Ghana Hernia Society, which included lectures on hernia epidemiology, surgical safety, mesh hernia repair technique, and local anesthesia administration for inguinal hernia repair. Thereafter, the trainees received hands-on training by the trainers through first observing and then performing hernia repairs with mesh under supervision. Next, 2 trainers independently determined each trainee's competence using a checklist based on the American Board of Surgery Operative Performance Assessment Form for open inguinal hernia.[24,25] Scores of 4 or 5 on a 5-point scale were considered sufficient to pass the course. The number of operations required to demonstrate competence ranged between 2 and 10. Only 1 surgeon trainee had any experience with mesh hernia repair prior to training.

Following completion of the course, the trainees performed the anterior tension-free mesh repair according to Lichtenstein under local anesthesia using a commercial polypropylene full-weight mesh (7.6 × 15 cm). This mesh was chosen because it was the only low-cost mesh available in Ghana. We purchased this mesh in Ghana for $11 (in US dollars) per piece. Patients were assigned to their surgical care clinician

based on availability of the surgeon, medical doctors, and operating room schedule. The surgeries were completed over the course of 6 months during 4 surgical camps.[26] During the camps, 2 operating rooms were cleared of elective cases, allowing for up to 6 hernia repairs per room per day. This structure permitted maximal surgical productivity during a limited period.

Preoperatively, the patients were given 1 prophylactic dose of amoxicillin clavulanate, 1.2 g, intravenously, which is the standard antibiotic prophylaxis for hernia surgery at the study site hospital. A 1:1 mixture of bupivacaine, 0.25%, and lidocaine, 1%, was used to administer local anesthesia by the infiltration technique according to Lichtenstein.[27] One case was converted from local to general anesthesia owing to the large size of the hernia and patient intolerance of the procedure. The World Health Organization Surgical Safety Checklist was used during each case.[28] All wounds were closed using nylon vertical mattress sutures. Following surgery, the patients were observed overnight, which is standard care for hernia repair in Ghana. Wounds were dressed in a sterile fashion for discharge and patients were followed up at 1 week for a wound check. The program paid one-half of the hospital and operation fees for patients (approximately $30 of $60 total) and provided the mesh without cost.

Study Participants and Study Site

Following completion of the training program outlined above, all patients who underwent operations by the trainees were invited and all gave consent to participate. This population consisted of men (≥18 years) with primary, reducible inguinal hernia. Men with bilateral hernias could participate and received repair on the most symptomatic side. Exclusion criteria included an American Society of Anesthesiologists classification score of 3 and above, obvious ongoing alcohol or drug abuse, as well as confirmed or suspected coagulopathy. The study was undertaken at Volta Regional Hospital in Ho, Ghana, which is a 306-bed referral hospital for the Volta Region under the management of the Ghana Health Service. Ghana is a lower middle-income country located in West Africa. It has a population of 28 million and 8.4% of the people live in extreme poverty on less than $1.90 USD per day.[29] Ghana ranks as 140 of 189 countries and territories on the Human Development Index.[30]

Study Outcomes

The primary end point of the study was hernia recurrence after 1 year. Recurrence was defined as a palpable mass with cough impulse on the same side as the repair. The secondary end points included postoperative complications after 2 weeks as well as patient satisfaction, pain, and self-assessed health status 1 year after repair. The postoperative complications included infection, hematoma, seroma, impaired wound healing (defined as failure of skin closure at 2 weeks), severe pain, urinary retention, or other severe adverse events. Patients were asked if they were satisfied with the result of the operation. Pain was assessed using the Inguinal Pain Questionnaire (IPQ) score for groin symptoms. The IPQ is a 7-level scale on which a score of 1 represents no pain, 2 to 3 indicates mild pain that does not interfere with daily activities, 4 to 6 indicates pain that is severe and interferes with daily activities, and 7 represents the maximum possible pain with need for immediate medical attention.[31] A Health Thermometer (inspired by the EuroQol 5D tool) scale ranging from 0 (worst imaginable health) to 100 (best imaginable health) was used to evaluate the self-perceived general health of the study participants before and 1 year after the procedure.[32]

Data Collection

Patients were interviewed in Ewe, Twi, or English based on their preference. The information collected included medical history, responses to the IPQ and the Health Thermometer, and a physical examination. This information was collected preoperatively and at follow-up visits 2 weeks and 1 year after the surgery. A medical doctor or surgeon blinded to the identity of the operating doctor performed the postoperative physical examination to assess for complications and hernia recurrence.

Statistical Analysis

The hernia recurrence rate in the study of outcomes after low-cost mesh repair in Uganda was 1%.[22] We assumed a slightly higher recurrence rate of 2% in our real-world program. Based on a noninferiority design, the assumptions of 80% power, 5% significance level, 5% noninferiority limit, and expected success rate of 98% (2% hernia recurrence rate) resulted in a sample size of 97 individuals. Correcting for an expected 20% loss to follow-up, we calculated a sample size of 121 in each group for a total of 242 participants.

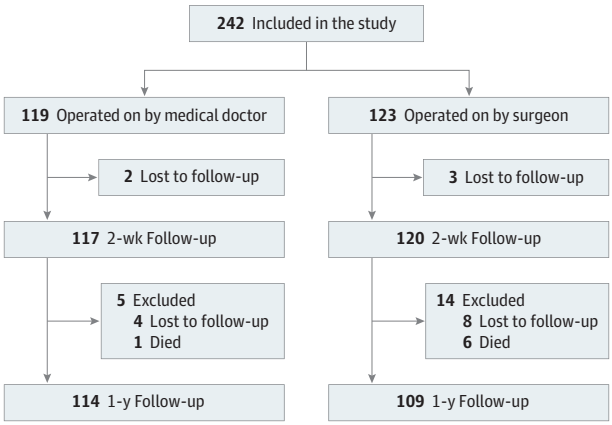
A descriptive analysis was performed, and the 2 study arms were compared using independent-sample *t* test for continuous variables and Pearson χ^2 or Fisher exact test as appropriate for counts. Absolute difference was calculated for the study end points and is presented with a 95% CI. For the primary outcome, which was used for the sample size calculation of this noninferiority study, a 1-sided test was done: only the lower margin is presented. Noninferiority margins were not defined for the secondary end points; therefore, 2-sided tests were used for the analysis of these results. A *P* value <.05 was considered statistically significant. The data were analyzed using Stata, version 15.1 (StataCorp LLC).

Results

A total of 242 patients were included in the study (**Figure**). Of these, 119 patients underwent operations performed by a medical doctor and 123 underwent operations performed by a surgeon. The preoperative characteristics of the patients are summarized in **Table 1**. The only statistically significant difference between the 2 study groups was self-assessed health status. Patients whose operations were performed by medical doctors self-identified as being healthier than those whose operations were performed by surgeons (mean [SD] score, 70.2 [14.0] vs 66.5 [13.4]; *P* = .02).

At 2 weeks postoperatively, 237 of the patients (97.9%) were seen in follow-up. The 5 patients who were not evaluated could not be contacted using the details they had given on enroll-

Figure. Flowchart of Patients Included in the Study



When patients excluded from analysis were deducted, the denominator at the start of the study was 242; at the 2-week follow-up, 237; and at the 1-year follow-up, 223. Some patients who were not seen at the 2-week follow-up were located and evaluated at the 1-year follow-up.

Table 1. Preoperative Characteristics of the Study Participants

Characteristic	Medical Doctor (n = 119)	Surgeon (n = 123)
Age, mean (SD), y	51.4 (15.8)	52.9 (17.0)
ASA classification score of 1, No. (%)	102 (85.7)	96 (78.7)
BMI, mean (SD)	21.9 (2.8)	21.7 (3.2)
Scrotal hernia, No. (%)	64 (53.8)	64 (52.0)
Duration of hernia, mean (SD), y	7.3 (8.0)	9.2 (10.2)
Smoker, No. (%)	7 (5.9)	11 (8.9)
IPQ score, mean (SD)[a]	3.3 (1.9)	3.6 (1.9)
Self-assessed health status score, mean (SD)[b,c]	70.2 (14.0)	66.5 (13.4)

Abbreviations: ASA, American Society of Anesthesiologists; BMI, body mass index (calculated as weight in kilograms divided by height in meters squared); IPQ, Inguinal Pain Questionnaire.

[a] The IPQ scale is 1, no pain; 2 to 3, mild pain that does not interfere with daily activities; 4 to 6, pain that is severe and interferes with daily activities; and 7, maximum possible pain with need for immediate medical attention.

[b] Health Thermometer scale, ranging from 0 (worst imaginable health) to 100 (best imaginable health), was used.

[c] The only statistically significant difference between the groups ($P = .02$).

ment. One year postoperatively, 223 of the patients (92.1%) were seen at follow-up. Seven patients had died; 1 in the medical doctor group and 6 in the surgeon group (**Table 2**). Information about these deaths was obtained from interviews with next of kin and from medical record reports from the study site hospital (eTable in the Supplement). Patients who died were excluded from analysis of the 1-year primary and secondary end points of the study. The 12 patients who were lost to follow-up at 1 year were also excluded from the final analysis.

At 1 year, 4 recurrent hernias (1.8%) were identified (Table 2). One recurrence (0.9%) occurred in the medical doctor group and 3 recurrences (2.8%) occurred in the surgeon group. All recurrences were found in patients with large scrotal hernias measuring greater than 22 cm from the pubic tubercle to the inferior margin of the hernia. With the lower limit of the 1-sided 95% CI being −4.8 percentage points, these results suggest that hernia repairs performed by medical doctors were not inferior to those performed by surgeons ($P < .001$).

Of the patients who presented for follow-up at 2 weeks, 63 individuals (26.6%) had developed at least 1 postoperative complication (**Table 3**). Hematoma was the second most common complication and was documented in 21 patients (8.9%). In addition, 13 patients (5.5%) developed seroma. One patient had to undergo a second operation for evacuation of a hematoma. The rate of superficial infection and impaired wound healing was higher among patients who underwent operations by medical doctors compared with surgeons; however, these differences were not statistically significant (superficial infection: 13 [11.1%] vs 6 [5.0%], $P = .08$; impaired wound healing: 15 [12.9%] vs 7 [5.8%], $P = .06$). All infections resolved with oral antibiotic therapy. No reoperation was required owing to infection and there was no mesh infection.

There were no statistically significant differences between medical doctors and surgeons in postoperative complications (34 [29.1%] vs 29 [24.2%], $P = .39$), patient satisfaction (112 [98.2%] vs 108 [99.1%], $P > .99$), severe chronic pain (1 [0.9%] vs 4 [3.7%], $P = .41$), or self-assessed health (85.9 vs 83.7 of 100; $P = .27$) (**Table 4**). Most (220 [98.7%]) patients were satisfied with the result of the operation. Overall, the mean self-assessed health status improved from 68.3 before the surgery to 84.8 one year after surgery ($P < .001$). There was no significant difference in mean self-assessed health status between the study groups. Chronic pain of levels 4 to 5 according to the IPQ scale was seen in 5 patients (2.2%); however, all 5 patients reported less pain postoperatively than before the surgery.

Discussion

This study suggests that inguinal hernia repair with mesh can be performed by medical doctors with noninferior 1-year recurrence rates compared with surgeons. The distribution of the secondary end points, including postoperative complications, chronic pain, and patient satisfaction, were also similar after inguinal hernia repair with mesh performed by medical doctors and surgeons.

This study contributes to the literature on surgical task sharing by supporting the sharing of surgical tasks between surgeons and medical doctors in Ghana. To our knowledge, there has been no previous evidence that medical doctors could safely and adequately perform inguinal hernia repair, despite this being common practice in several sub-Saharan African countries. The findings of this study have implications for surgical workforce development in both high- and low-income countries. Going forward, we plan to use surgical task sharing in the implementation of mesh hernia repair capacity-building programs in Ghana and other countries in the region. By increasing the number of clinicians trained in the highest quality method of inguinal hernia repair, there is potential that the burden of hernia disease may begin to decrease in Ghana and other sites.

Table 2. One-Year Hernia Recurrence and Mortality Among the Study Participants

Primary Outcome	No. (%)		Absolute Difference, % (95% CI)[a]	*P* Value
	Medical Doctor (n = 114 Patients)	Surgeon (n = 109 Patients)		
Hernia recurrence	1 (0.9)	3 (2.8)	−1.9 (−4.8)	<.001
Death	1 (0.9)	6 (5.5)	−4.3 (−8.7 to 0.1)	.12

[a] Confidence of absolute difference was 1-sided for the primary outcome of hernia recurrence at 1 year. Analysis of death is presented with a 2-sided 95% CI.

Table 3. Secondary End Points at 2 Weeks

End Point	No. (%)		Absolute Difference, % (95% CI)	*P* Value
	Medical Doctor (n = 117 Patients)	Surgeon (n = 120 Patients)		
Any postoperative complication	34 (29.1)	29 (24.2)	4.9 (−6.4 to 16.1)	.39
Distribution of postoperative complications				
Impaired wound healing	15 (12.9)	7 (5.8)	7.1 (−0.31 to 14.5)	.06
Superficial infection	13 (11.1)	6 (5.0)	6.1 (−0.8 to 13.0)	.08
Hematoma	12 (10.3)	9 (7.5)	2.8 (−4.5 to 10.0)	.45
Seroma	5 (4.3)	8 (6.7)	−2.4 (−8.2 to 3.4)	.42
Severe pain	2 (1.7)	1 (0.8)	0.9 (−2.0 to 3.7)	.62
Other complication	3 (2.6)	0	2.6 (−0.3 to 5.4)	.12
Intervention for complication[a]	3 (2.6)	2 (1.7)	0.9 (−2.8 to 4.6)	.68

[a] Including drainage of hematoma or seroma, stitching of bleeding skin edges, and reoperation for evacuation of hematoma.

Table 4. Secondary End Points at 1 Year

End Point	No. (%)		Absolute Difference, % (95% CI)	*P* Value
	Medical Doctor (n = 114 Patients)	Surgeon (n = 109 Patients)		
Lesser degree of groin symptoms than before the operation	110 (96.5)	106 (97.3)	−0.76 (−5.3 to 3.8)	.74
IPQ score, mean (SD)	1.3 (0.6)	1.4 (0.8)	−0.06 (−0.2 to 0.1)	.52
Distribution of IPQ[a]				
IPQ 1	85 (74.6)	80 (73.4)	1.2 (−10.4 to 12.7)	.41
IPQ 2-3	28 (24.6)	25 (22.9)	1.6 (−9.5 to 12.8)	
IPQ 4-5	1 (0.9)	4 (3.7)	−2.8 (−6.7 to 1.1)	
Self-assessed health status score, mean (SD)[b]	85.9 (14.6)	83.7 (16.0)	2.3 (−1.8 to 6.3)	.27
Change from preoperative score, mean (SD)	15.9 (17.7)	17.2 (17.4)	−1.34 (−6.0 to 3.3)	.57
Patient satisfied with result of surgery	112 (98.2)	108 (99.1)	−0.8 (−3.8 to 2.2)	>.99

Abbreviation: IPQ, Inguinal Pain Questionnaire.

[a] The IPQ scale is 1, no pain; 2 to 3, mild pain that does not interfere with daily activities; 4 to 6, pain that is severe and interferes with daily activities; and 7, maximum possible pain with need for immediate medical attention.

[b] Health Thermometer scale, ranging from 0 (worst imaginable health) to 100 (best imaginable health), was used.

The strength of this study is that it was prospective in design with a high follow-up rate. To our knowledge, this study represents the largest and longest follow-up of mesh hernia repairs performed by African doctors in sub-Saharan Africa. The internal validity is therefore high. This work demonstrates that rigorous prospective clinical research is possible in global surgery, which is an important contribution to the evolving literature in this nascent field.

In general, the rates of postoperative complications in this study were comparable to those reported in the literature. The overall hernia recurrence rate of 1.8% compares favorably with results from both low- and high-income settings (0.5%-3.8%).[20,22,33,34] Hematoma was the second most common complication and was documented in 21 patients (8.9%). In addition, 13 patients (5.5%) developed seroma. One patient had to undergo a second operation for evacuation of a hematoma. Given that over 50% of the patients had scrotal hernias, often of considerable size, even higher rates of hematoma and seroma could have been expected. After 1 year, most patients were satisfied with the result of the surgery and almost all patients had fewer symptoms than before the surgery. Five patients (2.2%) had severe chronic pain, which is similar to rates of severe postoperative pain reported in other studies (2%-4%).[35]

Wound infection requiring antibiotic therapy occurred in 8.0% of the study patients. Although the infection rate was higher in the medical doctor group, this difference was not statistically significant. All infections resolved with oral antibiotic therapy and no deep or mesh infections were found. The infection rate is higher compared with that in the previous study in Uganda (3.4%) and also compared with findings from high-income settings (0%-4.8%).[22,36] This greater level could indicate a de facto increased risk of infection in the study setting compared with other settings, as well as a difference in assessment of postoperative infection and when antibiotics are prescribed. Infection prevention and control are paramount

and an important focus of quality improvement initiatives in global surgery. More education and assurance of intraoperative sterile practices, prophylactic antibiotic administration, and postoperative wound care will be included in further development of the training program.

Death was not an end point in this study but occurred in 7 cases, seemingly unrelated to the hernia or the hernia repair. Six of these patients had been operated on by surgeons and 1 had been operated on by a medical doctor (eTable in the Supplement). Although all of the program patients were assessed as American Society of Anesthesiologists group 1 or 2 preoperatively, it is likely that some had undiagnosed conditions related to lack of regular access to primary health care. It is also likely that some patients developed additional medical conditions during the follow-up period. Because the 1-year mortality rate is fairly high, increased attention to preoperative assessment as well as accounting for potential mortalities in sample size calculation will be necessary in future studies.

Limitations

There are some limitations of the study. Owing to considerations by 1 of the institutional review boards, the study was not randomized. In a randomized trial, potential bias would have been excluded by design. In this study, allocation of patients to the operating surgeon or medical doctor was done based on clinician availability within the structure of 4 high-volume surgical camps. While this allocation may introduce some unmeasured bias, patient characteristics were similar in both study arms, and therefore the results should be considered valid. The primary outcome—hernia recurrence—was measured after 1 year. Because postoperative recurrence is possible after 1 year, this length of follow-up is a study limitation.[33,34] Another limitation was the small number of trainees. The trainees were selected to learn the mesh technique with the requirement of experience in tissue hernia repair. They also had to be available for the training and surgery camps. The number of individuals who could potentially participate was relatively small. The external validity is therefore limited. The study does not show that any medical doctor should be trained to perform mesh hernia repair in any hospital. Instead, it suggests that both medical doctors and surgeons who have interest and aptitude for surgery and hernia repair can be taught to perform this procedure safely and effectively.

Conclusions

This study shows that medical doctors can be trained to perform elective inguinal hernia repair with mesh in men with good results and high patient satisfaction in a low-resource setting. These findings support the use of surgical task sharing to develop the surgical workforce and combat the significant burden of disease associated with inguinal hernia globally.

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Concept and design: Beard, Ohene-Yeboah, Sims, Nordin, Wladis, Harris, Löfgren.
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