World Journal of Gastroenterology

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DOI: 10.3748/wjg.v21.i16.5056

World J Gastroenterol 2015 April 28; 21(16): 5056-5071
ISSN 1007-9327 (print) ISSN 2219-2840 (online)

Non-physician endoscopists: A systematic review

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Received: July 27, 2014
Peer-review started: July 27, 2014
First decision: September 15, 2014
Revised: September 18, 2014
Accepted: December 14, 2014
Article in press: December 22, 2014
Published online: April 28, 2015

Abstract

AIM: To examine the available evidence on safety, competency and cost-effectiveness of nursing staff providing gastrointestinal (GI) endoscopy services.

METHODS: The literature was searched for publications reporting nurse endoscopy using several databases and specific search terms. Studies were screened against eligibility criteria and for relevance. Initial searches yielded 74 eligible and relevant articles; 26 of these studies were primary research articles using original datasets relating to the ability of non-physician endoscopists. These publications included a total of 28883 procedures performed by non-physician endoscopists.

RESULTS: The number of publications in the field of non-specialist gastrointestinal endoscopy reached a peak between 1999 and 2001 and has decreased thereafter. 17/26 studies related to flexible sigmoidoscopies, 5 to upper GI endoscopy and 6 to colonoscopy. All studies were from metropolitan centres with nurses working under strict supervision and guidance by specialist gastroenterologists. Geographic distribution of publications showed the majority of research was conducted in the United States (43%), the United Kingdom (39%) and the Netherlands (7%). Most studies conclude that after appropriate training nurse

endoscopists safely perform procedures. However, in relation to endoscopic competency, safety or patient satisfaction, all studies had major methodological limitations. Patients were often not randomized (21/26 studies) and not appropriately controlled. In relation to cost-efficiency, nurse endoscopists were less cost-effective per procedure at year 1 when compared to services provided by physicians, due largely to the increased need for subsequent endoscopies, specialist follow-up and primary care consultations.

CONCLUSION: Contrary to general beliefs, endoscopic services provided by nurse endoscopists are not more cost effective compared to standard service models and evidence suggests the opposite. Overall significant shortcomings and biases limit the validity and generalizability of studies that have explored safety and quality of services delivered by non-medical endoscopists.

Key words: Nurse endoscopist; Cost-benefit; Service model; Patient satisfaction; Outcome parameter

Core tip: A systematic review was performed to examine the available evidence on safety, competency and cost-effectiveness of nursing staff providing gastrointestinal endoscopy services. Most studies conclude that after appropriate training nurse endoscopists safely perform procedures. Contrary to general beliefs, endoscopic services provided by nurse endoscopists are not more cost effective compared to standard service models due largely to the increased need for subsequent endoscopies, specialist follow-up and primary care consultations. The empirical evidence that supports non-physician endoscopists is limited to strictly supervised roles in larger metropolitan settings and mainly flexible sigmoidoscopy and upper endoscopy for asymptomatic or low complexity patients.

Stephens M, Hourigan LF, Appleyard M, Ostapowicz G, Schoeman M, Desmond PV, Andrews JM, Bourke M, Hewitt D, Margolin DA, Holtmann GJ. Non-physician endoscopists: A systematic review. *World J Gastroenterol* 2015; 21(16): 5056-5071 Available from: URL: http://www.wjgnet.com/1007-9327/full/v21/i16/5056.htm DOI: http://dx.doi.org/10.3748/wjg.v21.i16.5056

INTRODUCTION

Nurse endoscopy training and delivery of endoscopic services was first reported in the United States more than 35 years ago for flexible sigmoidoscopy (FS)[1]. Several studies soon emerged, confirming that nursing staff with appropriate training and supervision could adequately perform endoscopic procedures such as FS. Other studies have since established that nurse endoscopists can safely perform upper endoscopies and colonoscopies. In an era where safe, yet cost-effective, policies run at the forefront of stakeholders' minds, the question of how nursing staff can undertake additional roles in the endoscopic suites is continually raised. After more than 35 years, it appears timely to review the available evidence surrounding the role of nurse endoscopists. To our knowledge, there have been no systematic reviews of the literature that have examined the full body of evidence surrounding uptake, safety, accuracy and most importantly, the cost-effectiveness of nurse endoscopists.

MATERIALS AND METHODS

Skill of endoscopy

Competent endoscopy has both procedural (manual dexterity) and cognitive aspects. Procedural skills refer to the ability of endoscopists to insert/withdraw the endoscope, navigate the alimentary tract with acceptable views and perform further actions such as biopsy, polypectomy or other interventions. Procedural (technical) competence necessitates that these actions are executed in a timely manner that exposes the patient to acceptable risk of complications. Procedural or technical skill is generally measured by direct observation of the procedure[2] alongside several quality indicators such as overall procedural time, caecal intubation time, caecal intubation rate, polyp/adenoma detection rate, depth of insertion, adequacy of views on review of video footage, rate of complications and patient satisfaction.

On the other hand, cognitive (or non-technical) skill refers to the ability of endoscopists to perform more complex tasks beyond the procedure itself. These include: (1) recognizing and interpreting gross pathology; (2) interpreting the patient's clinical picture in relation to endoscopic findings; (3) understanding the patient's current clinical risk and how this could change with/without further endoscopic treatment; (4) knowledge of any viable alternatives to endoscopic procedures that could better serve the patient; (5) recommending treatments/further investigations appropriate to the severity of pathology seen; and finally; and (6) understanding the indications and contraindications for the proposed procedure.

These cognitive elements are important during the composition of the report and any follow-up by the endoscopists, as well as during the procedure itself. By their nature, the cognitive aspects of endoscopy do not lend themselves towards easy measurement, especially when comparing competence between study groups. Assessment of endoscopists' reports by consultant gastroenterologists (gold standard) after review of video footage has been performed with some merit, but assessment is often subjective and limited to measuring sensitivity and specificity of detecting

simple gross pathology[3,4].

Physician and surgical trainees in gastroenterology and surgical specialities undergo extensive training before providing independent endoscopic services. This training addresses both the procedural and cognitive aspects of endoscopy, with procedural competency being obtained more rapidly compared to cognitive competency, which requires years of comprehensive clinical training. Indeed, many studies have shown that a high level of procedural competency for FS is typically achieved after around 100-200 supervised procedures, with higher numbers needed for colonoscopy/upper endoscopy.

This applies regardless of whether the trainees are junior doctors, advanced trainees, fellows, or non-physician personnel[5-13]. It is unlikely however, that nurses and other non-physician endoscopists routinely acquire the same level of cognitive competency as physician endoscopists or other medically qualified and trained staff. This cognitive aspect, intrinsic to the procedure, requires the ability to make a well-reasoned decision within the context of the patient's full clinical picture, to take responsibility for decisions made, to manage efficiently complications and to guide subsequent follow-up. This is a style of thinking which is fostered in physicians through years of training, yet generally not taught in nursing education, which tends to be more protocol based. On the other hand it might be argued that these cognitive skills are not required to perform a simple procedure, which requires a clearly defined but limited set of skills. However, from the perspective of the healthcare system as a whole, one needs to examine not only the actual procedure, but also all costs involved in its delivery, and this necessarily includes an evaluation of cost-effectiveness of the entire "episode of care".

This systematic review aims to assess the current evidence to support the provision of diagnostic or therapeutic endoscopic services by trained non-physicians including nurses, and the evidence regarding cost-effective delivery of services that meet patient needs. We specifically aim to assess: (1) the evidence that non-physician endoscopists can acquire the required procedural and cognitive skills to deliver endoscopic services; (2) the cost-benefit analysis of procedures performed by nurses and other non-physicians as compared to medical and surgical specialists, and (3) characterize the service models that have been used so far.

Search strategy

We devised the following Boolean search terms: nurse and endoscopist ("nurse and performed" or "delivered") or "nurse practitioner" and ("endoscopy" or "colonoscopy" or "flexible sigmoidoscopy" or "esophagogastroduodenoscopy"); ("non-medical" or "non-physician" or "non-medical" or "non-physician" or "physician assistant") and "endoscopy". We searched each of the following electronic databases using each of the above search terms individually: Cochrane Library; MEDLINE; CINAHL; Google Scholar. The most recent search was performed January 2014.

Eligibility and relevance

To be deemed eligible and relevant for inclusion in the review, studies/articles must have described or referred to non-medical personnel (*i.e.,* nurses, physicians assistants, technicians, non-medical personnel or those not practicing as a doctor) being the primary proceduralists for any form of gastrointestinal endoscopy. Non-medical personnel needed to be included in the review as there is discrepancy in the terminology in literature. Studies that were solely focused on capsule endoscopy or nurses assisting in placing percutaneous endoscopic gastrostomy tubes were excluded from the systematic search part of the review. Studies were excluded if they were not published in a peer-reviewed journal. All languages and age ranges were included. There were no date limits.

Data extraction

For all eligible studies, any entries that were identified as "comments" on other articles were removed from any analyses. The remaining articles were stratified into "primary research measuring endoscopists' performance" or "other". For each primary research study, the following information was extracted: author names and year of publication, country of origin, total number of procedures performed by nurses/non-medical endoscopists, degree of supervision of endoscopists, clinical setting, whether there was true randomization of patients, number and type of proceduralists, potential biases, outcome parameters used by the study and important outcomes. If studies referred to other pieces of research or articles that were not discovered by the systematic search, but were eligible and relevant, they were also included in the review.

Statistical analysis

The number of publications (primary research or otherwise) by year, publications by country and total non-physician procedures reported were assessed. The data were extracted from the identified primary research articles independently by two of the authors (MS and GH). These data were compared and discrepancies assessed and agreement reached when required. The review of the data also included an assessment of the overall quality of the studies. For this assessment, key criteria such as randomization, concealment of randomization, the risk of selective reporting and other relevant indicators of bias[14] and study quality were assessed with the results tabulated in keeping with the Cochrane Collaboration's Risk of Bias Assessment. A meta-analysis of the data was

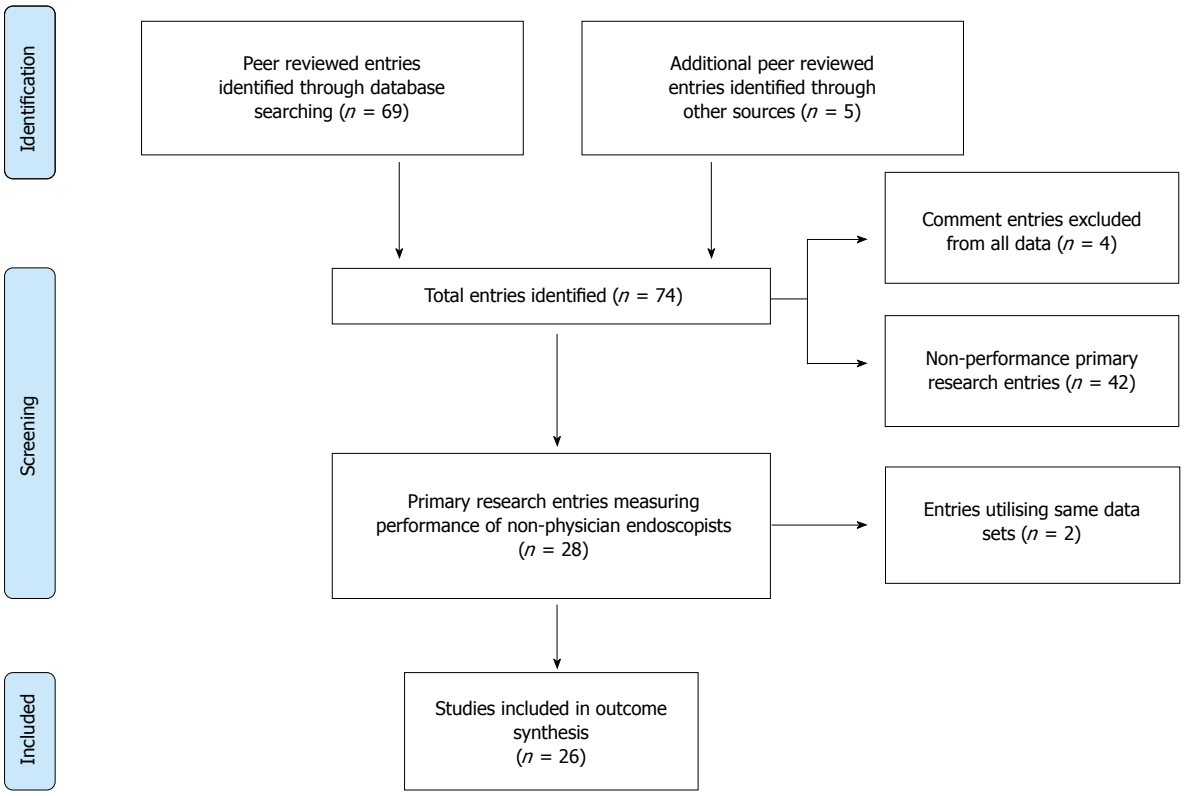

Figure 1 Flow chart of search methodology and article selection.

not possible due to the heterogeneity of the studies. Where original data were re-reported in second or third publications, only the original data were included.

RESULTS

The literature search identified 74 publications, of which 4 were identified as "comments" and removed from any further analysis. Publications were dated between March 1977 and September 2013. In these 70 studies, a total of 28883 non-physician endoscopies had been documented. Twenty eight (40%) were identified as primary research measuring endoscopists' performance with definable outcome parameters. Two studies re-reported original data and excluded leaving 26 studies suitable for further analysis (Figure 1 and Table 1). Of these primary research studies there were 17476 documented non-physician endoscopies (n = 17476).

Quality indicators

The key quality indicators of the studies are summarized in Table 2. There was a widespread lack of randomization or blinding of concealment. In addition some of these open, uncontrolled and unblinded studies[5-7,10,12,15-18] appear to represent descriptive "verifications" of training programs that were developed. Overall the quality of these studies was very limited.

Publication activity and geographic distribution

Publication activity was quantified using all 70 published papers and did not include "comment" publications. Publication activity graphed by 3-year periods (Figure 2) demonstrates a rapid increase in publications between 1990 and 2001, peaking at 15 articles for the 3-year period 1999 to 2001. Over the past 9 years, the rate has slowly decreased with fewer than 10 publications in the last 3 years. This decline is mirrored by a decline in documented procedures performed by non-physician endoscopists (Figure 3). Of note, 96% (2030/2080) of documented procedures, and 75% (3/4) of original datasets in the last 3 years have come from one (Dutch) research group. The overall geographic distribution of publication activity is demonstrated in Figure 4.

Non-physician endoscopy performance measures and comparisons, service models and cost-efficiency models

Twenty eight articles were identified in literature that measured the performance of non-physician endoscopists (Table 1). Of these, Williams *et al*[19], Richardson *et al*[20] and Williams *et al*[21] used the same datasets leaving 26 studies suitable for analysis. Seventeen out of 26 original datasets related to FSs (n = 12218), 5 to upper GI endoscopy (n = 2150) and 6 studies to colonoscopy (n = 2559). Several datasets related to 2 types of procedures. 19% of all datasets

Table 1 Summary table of all competency research regarding medical and nurse and other non-physician endoscopists

Publication	Setting	Non-physician proce-dures	Supervision	True randomization of patients?	Procedurists	Potential biases	Outcome parameters	Modality	Outcome
Rosevelt *et al*[8], 1984	Metropolitan Tertiary Centre, United States	825	Yes	No	1 NE	Patient selection bias Endoscopist selection bias Level of assistance not documented	Polyp detection rate Complications	FS	Polyp detection rate of 8.7% No complications
Schroy *et al*[4], 1988	Metropolitan Tertiary Centre, United States	100	Yes	No	1 NE	Patient selection bias Endoscopist selection bias Level of assistance not documented Concordance criteria not given	Polyp detection rate Concordance of findings with expert opinion	FS	Polyp detection rate of 36% Video review showed k = 0.72 concordance with GC Nurse sensitivity = 75%, specificity = 94%
DiSario *et al*[15], 1993	Metropolitan Tertiary Centre, United States	80	Yes	Yes	5 NEs 5 GRs	Endoscopist selection bias Level of assistance not documented 1 NE excluded due to incompetency after training Comparison of outcome groups for missed lesions not calculated	Insertion depth Identification of anatomy Complications Procedure time Missed lesions	FS	Polyp detection rate of 24% Insertion depth, complications and procedure time similar between groups NEs missed more lesions and missed more anatomy
Maule[7], 1994	Metropolitan Tertiary Centre, United States	1881	Yes	No	4 NEs 2 GCs	Endoscopist selection bias Complicated patient referred away from NEs Level of assistance not documented	Insertion depth Complications Polyp detection rate Patient satisfaction	FS	GCs had significantly deeper insertion depths Similar polyp detection rate Similar patient satisfaction
Moshakis *et al*[16], 1996	Metropolitan Tertiary Centre, United Kingdom	50	Yes	No	1 NE 1 GC	Endoscopist selection bias Patient selection bias NE was compared to GC who performed training Level of assistance not documented Method of quality scoring not given	Insertion depth "Quality and accuracy"	FS	Insertion depth, quality and accuracy were similar between comparison groups
Duthie *et al*[6], 1998	Metropolitan Tertiary Centre, United Kingdom	205	Not specified	No	1 NE	Endoscopist selection bias Patient selection bias Criteria for "successful procedure" not given	Successful procedure when compared to various other imaging modalities	FS	93% of procedures considered "successful"
Schoenfeld, Cash *et al*[17], 1999	Metropolitan Tertiary Centre, United States	114	Yes	No	1 NE 3 GFs 3 Surgical Consultants	Endoscopist selection bias Patient selection bias Level of assistance not documented	Depth of insertion Procedure time Polyp detection rate Patient satisfaction Complications	FS	Surgeons had less depth of insertion than NEs or GFs NEs had longer procedures than GFs or surgeons Polyp detection rate similar No complications
Schoenfeld, Lipscomb *et al*[10], 1999	Metropolitan Tertiary Centre, United States	151	Yes	Yes	3 NEs 4 GCs	Endoscopist selection bias Patient selection bias Level of assistance not documented High threshold for detecting difference in polyp detection rate	Polyp detection rate Depth of insertion Complications	FS	Polyp detection rates similar between groups (43%-45%) GCs had much greater depth of insertion No complications
Wallace *et al*[9], 1999	Metropolitan Tertiary Centre, United States	2323	Yes	No	1 NE 2 PAs 15 GCs	Endoscopist selection bias Patient selection bias Level of assistance not documented	Depth of insertion Polyp detection rate Complications	FS	GCs had significantly greater depths of insertion compared with NE+PAs Polyp detection rate similar between groups (23%-27%) No complications

Schoen *et al*[26], 2000	Metropolitan Tertiary Centre, United States	660	Not specified	No	1 PE 1 GC 1 MC	Endoscopist selection bias Patient selection bias Level of assistance not documented	Patient satisfaction	FS	Similar patient satisfaction between groups
Shapero *et al*[27], 2001	Metropolitan Tertiary Centre, Canada	488	No	No	2 NEs	Endoscopist selection bias Patient selection bias Level of assistance not documented	Polyp detection rate Complications Depth of insertion Procedure time	FS	Average depth of insertion 52.9 cm 8.4 min average procedure time Polyp detection rate of 15.4%
Jain *et al*[28], 2002	Metropolitan Tertiary Centre, United States	5000	No	No	Not specified No physicians	Unknown endoscopists Patient selection bias Level of assistance not documented No comparison	Polyp detection rate No complications	FS	No major complications polyp detection rate of 13.3%
Meenan *et al*[29], 2003	Metropolitan Tertiary Centre, United Kingdom	25	Yes	No	1 NE 4 GFs	Endoscopist selection bias Patient selection bias Level of assistance not documented Views by NE were limited to the esophagus	Adequacy of views obtain by radial ultrasound by endoscopy	EGD	NEs had consistently lower quality scores
Smale *et al*[30], 2003	Metropolitan Tertiary Centre, United Kingdom	1487	Yes	No	2 NEs 15 mixed medical/ surgical physicians	Endoscopist selection bias Patient selection bias Level of assistance not documented Complicated patients excluded Retrospective and prospective	Differences in sedation Patient satisfaction	EGD	No difference between groups for sedation or patient satisfaction Subjectively, nurses reporter fewer studies as normal
Wildi *et al*[22], 2003	Metropolitan Tertiary Centre, United States	40	Yes	No	1 NE 1GC	Endoscopist selection bias Patient selection bias Level of assistance not documented Method of assessment not given	Concordance of findings with GC	EGD	NE had sensitivity of 75% and specificity of 98% with GC as gold standard
Nielsen *et al*[12], 2005	Metropolitan Tertiary Centre, Denmark	69	Yes	No	2 NEs Unknown number of physicians	Endoscopist selection bias Patient selection bias Level of assistance not documented	Patient satisfaction	FS	Nurses had better patient satisfaction than physicians
Meining *et al*[3], 2007	Metropolitan Tertiary Centre, United Kingdom	190	Yes	Yes	2 NEs 1 GC 2 GRs 1 Physician not specified 1 MC	Endoscopist selection bias Patient selection bias Level of assistance not documented Subjectivey, nurses tended to focus on the entire examination whilst physicians focused on the reason for referral	Adequacy of views for entire procedure Duration of procedure Use of sedation	EGD	Nurses had twice the amount of adequate views however took twice as long on average. Nurses used sedation more frequently
Williams *et al*[19], 2006 Williams *et al*[21], 2009	Nation-wide Metropolitan Tertiary Centres, United Kingdom	957	Yes	Yes	30 NEs 67 physicians (not specified)	Significantly higher numbers of patients changed schedule from physician to nurse (due	Patient satisfaction Adequacy of views Depth of insertion Endoscopic procedures performed Duration of examination Complications	EGD	Patient satisfaction favoured nurses No difference for depth of insertion Nurses took biopsies for histology in upper endoscopy and FS more frequently than physicians. There were more normal histology findings for nurses

Richardson *et al*[20], 2009							Need for assistance Need for subsequent follow up and investigation Cost-benefit analysis		Nurses were more likely to report sedation and procedural details whilst physicians were more likely to report diagnosis and suggested treatment. Nurses took biopsies for *H. pylori* more frequently No major differences in final diagnoses frequency between 2 groups. No serious complications Similar need for assistance. Nurses had greater follow-up cost per procedure whilst physicians had greater labor costs per procedure. Physicians had greater overall costs per procedure but greater patient improvement. Physicians were 87% more likely to be cost-effective than nurse endoscopists.
Koornstra *et al*[11], 2009	Metropolitan Tertiary Centre, Netherlands	300	Yes	No	2 NEs 1 GF 1 GC	Endoscopist selection bias Patient selection bias Level of assistance not documented	Caecal intubation rate Caecal intubation time Complications Patient satisfaction	Col	Similar caecal intubation rates/times (80%-90%) between GF and NEs but much lower/longer than GC after 150 procedures. Patient satisfaction similar between GF and NEs, less than for GC. Similar complication rate.
Maslekar, Hughes *et al*[31], 2010	Metropolitan Tertiary Centre, United Kingdom	308	Not specified	No	1 NE 1 PA/T Several physicians not specified	Endoscopist selection bias Patient selection bias Level of assistance not documented NE and PA/Ts had less colonoscopies more FS	Complications Patient satisfaction	Col and FS	No difference between all 3 groups
Maslekar, Waudby *et al*[32], 2010	Metropolitan Tertiary Centre, United Kingdom	26	Yes	No	1 Surgical Registrar 1 PA/T	Endoscopist selection bias Patient selection bias Level of assistance not documented Patients needing resection excluded	Accuracy of endoscopists to gauge position in colon	FS	PA/T accuracy of 70% with Registrars accuracy of 80%, not statistically significant.
Shum *et al*[18], 2010	Metropolitan Tertiary Centre, HK	119	Yes	No	1 NE	No comparison group	Mean procedure time Depth of insertion Complications	FS	9.4 min average procedure time 53.5 cm average depth of insertion No major complications
Limoges-Gonzalez *et al*[44], 2011	Metropolitan Endoscopy Centre, United States	50	Yes	Yes	1 NE 2 GCs	Endoscopist selection bias Level of assistance not documented	Adenoma detection rate Caecal intubation rate Caecal intubation time Patient satisfaction Sedation use Complications	Col	Adenoma detection rate higher in NE (42%) than GCs (17%) All other parameters similar across both groups
de Jonge *et al*[33], 2012	Multi-metropolitan tertiary centre, Netherlands	162	Not specified	No (retrospective)	6 NEs 113 Staff not specified including GCs, GFs, surgeons, MCs	Data was retrospective review of reports	Overall caecal intubation rate Adenoma detection rate	Col	NEs and GFs and GCs found more adenomas and had greater caecal intubation rates (94%) than nongastroenterology staff, especially surgical

van Putten *et al*[34], 2012	Multi-metropolitan tertiary centre, Netherlands	1000	Yes	No	10 NEs	Endoscopist selection bias Patient selection bias	Unassisted caecal intubation rate Withdrawal time Adenoma detection rate Assistance requirements Patient satisfaction Complications	Col	Unassisted caecal intubation rate of 94% 23% of colonoscopies required assistance from GC Withdrawal time of 10 min Adenoma detection rate of 23% 1 perforation and 1 onset of atrial fibrillation 95% of patients satisfied with procedure
Massl *et al*[5], 2013	Multi-metropolitan tertiary centre, Netherlands	866	Yes	No	7 NEs 8 GFs	Endoscopist selection bias NEs had significantly lower ASA scores on patients Level of assistance not reported	Unassisted caecal intubation rate Caecal intubation time Complications Polyp detection rate	Col	Unassisted caecal intubation rate was significantly lower 77% for NE than GFs (88%). Polyp detection rate (45%), complications, withdrawal and intubation times were similar between groups. Crude cost-analysis showed a saving of €7.61 per colonoscopy where 1 GC supervises 3 NEs. Did not account for higher need for repeat colonoscopies due to incomplete procedures

Col: Colonoscopy; EGD: Esophagogastroduodenoscopy; FS: Flexible sigmoidoscopy; NE: Nurse endoscopist; GF: Gastroenterology fellow; GC: Gastroenterology consultant (attending); GR: Gastroenterology registrar/resident; PA/T: Physician's assistant or technician; MC: Medical (non-gastroenterology) consultant.

were from randomized patients (n = 1428); 64% of the original datasets were created utilizing $\leqslant$ 2 non-physician endoscopists (n = 5056). Eighty seven of the 91 (96%) non-physician endoscopists were nurse endoscopists. All studies were from centres in metropolitan regions with nurses working under strict supervision and guidance of gastroenterologists. It is important to note that all studies were conducted at tertiary hospitals or university centres in metropolitan locations. There are no data on unsupervised practice outside these closely monitored and well-defined settings.

Studies varied with regard to measures of procedural competence and outcome, however most used polyp/adenoma detection rate (FS and colonoscopy), insertion depth (FS), complications, patient satisfaction, procedure time and caecal intubation time/rate (colonoscopy). Studies attempting to measure cognitive competence were limited to Schroy *et al*[4]; Moshakis *et al*[16] and Wildi *et al*[22]. Williams *et al*[19] assessed post-procedural reports but not for content, only for the presence of specific details included on the report.

The available data do not allow a direct comparison or meta-analysis of the procedural performance of medical specialist and nurse endoscopists since the assessments were not standardized. In addition, substantial methodological limitations reduce the validity of results. For example, in studies comparing nurse and medical or surgical endoscopists, patients were seldom randomly allocated. However, based upon the data presented it appears reasonable to conclude that after appropriate training nurse endoscopists (and other non-medical staff) can perform specific endoscopic procedures under appropriate supervision by a medical or surgical specialist and within well-defined settings.

Cost-efficiency

Genuine cost-benefit analyses of non-physician endoscopists are scarce in the literature, although many articles claim non-physician endoscopists having a high likelihood of providing a cheaper per-procedure service. A crude cost-benefit analysis by Massl *et al*[5] suggested that a total saving of €7.61 (about USD10.39) per procedure could be achieved with a model of 1 senior gastroenterologist supervising 3 active nurse endoscopists. However these costs did not account for the total episode of care including follow-up procedures, follow-up consultations, histology and other factors. This is important given the likelihood that a procedure performed by a nurse endoscopist will require further follow-up for disease management. Indeed, a cost-benefit analysis from the United Kingdom took most of these factors into consideration in a national randomized National Health Service (NHS) based dataset[19-21] where 30 experienced nurse endoscopists performed both upper endoscopies and FS, but not colonoscopy (957 non-physician procedures). While physicians were more expensive per hour (£1.82/min *vs* £0.53/min), nurse endoscopists had significantly increased need for subsequent endoscopy, specialist follow-up and primary care follow-up at 1 year following their procedures. This lead to higher overall

Table 2 Assessment of the risk of bias assessments for studies included into this systematic review and key characteristics of data analysis

Publication	Sequence generation	Allocation concealment	Blinding of participants, personnel and outcome assessors	Incomplete outcome data	Selective outcome reporting	Other sources of bias	Study hypothesis and power calculation
Rosevelt[8], 1984	No randomization	No	No	Not specified	Likely, report was intended to describe a successful training program		No hypothesis, no statistics
Schroy *et al*[4], 1988	No randomization, review of videotape	No	No	Not specified	Report of an established service model. Review of videotapes Quality assurance		No statistics
DiSario[15], 1993	Computer generated randomization	Not specified	No	Not specified	Aim was to demonstrate that ".registered nurses could be trained to perform the flexible sigmoidoscopy in a similar to resident physicians'		Not powered to demonstrate equivalence, no formal power calculations
Maule[7], 1994	No randomization	Not specified	No	Not specified	The study was done to confirm that training of nurse endoscopists is feasible.		Hypothesis defined (no difference), no power calculation for equivalence study, oucome parameters not specified a priori
Moshakis *et al*[16], 1996	No randomization, no comparator	Not specified	No	Not specified	Report describes the successful training of one (1) nurse endoscopist		No hypotheses, no statistical analysis
Duthie *et al*[6], 1998	No randomization	No	No	Not specified	Evaluation of a training program that was developed and implemented by the authors (self-fulfilling prophecy)	Not evident	No hypothesis, no power calculation
Schoenfeld *et al*[17], 1999	No randomization, patients allocated to the 'first available provider'	No	No	Not specified	No evidence	Not evident	Several outcome parameters specified, but no hypothesis tested, no power calculation for equivalence.
Schoenfeld *et al*[10], 1999	Randomization of veterans referred for flexible sigmoidoscopy. Computer generated randomization	No	unknown	Not specified	Justifies the implemented clinical service model.		Several outcome parameters listed, but no specific hypothesis, power calculation provided (to identify differences, but not targeting equivalence)

Wallace *et al*[9], 1999	No randomization, nurse-coordinator assigned eligible patients to a physician or non-physician endoscopists based upon 'daily staffing assignments and patient time preference'	No	Unknown	Not specified	Justifies the implemented clinical service model.		No hypothesis stated, no power calculation
Schoen *et al*[26], 2000	No randomization	No	No	Not specified	Study targeted to demonstrate the good tolerability of flexible sigmoidoscopy	Gender distribution of patients was not equivalent across examiners, and the nurse practitioner did not have trainees working with her.	No hypothesis stated, no proper power calculation
Shapero *et al*[27], 2001	No randomization, allocation not clear	No	No	Not specified	Data justify the implemented clinical practice	Data are generated in the setting of CRC screening with flexible sigmoidoscopy, highly selective cohort.	Not done
Jain *et al*[28], 2002	No randomization	No	No	Not specified	Justification of implemented clinical practice	CRC screening utilizing flexible sigmoidoscopy, selective cohort	Not done
Meenan *et al*[29], 2003	No randomization	No	No	Not specified	Assessement of training progress		Not done
Smale *et al*[30], 2003	No randomization, part one retrospective analysis of endoscopy data base, second part prospective data collection	No	No	Not specified	Review and justification of clinical practice		Not done
Wildi *et al*[22], 2003	No randomization	No	No	Not specified	Sequential procedures Nurse endoscopist followed by physyician, potential effect of sequence.		Not done
Nielsen *et al*[12], 2005	No randomization	No	No	Not specified	Quality assurance of existing training program		Not done
Meining *et al*[3], 2007	No details in relation to the randomization process are provided. Patients unequally allocated to endoscopist or nurse	No	No	Reported but uneven numbers of 'Randomization failures (33 *vs* 0). Considerable number of patients excluded (only 367 out of 641 reported)	Review and justification of clinical practice	Primary outcome parameter was stated as "appropriate diagnosis", this outcome parameter was not reported.	Not done
Williams *et al*[19], 2006 Williams *et al*[21], 2009 Richardson *et al*[20], 2009	Randomization of patients to nurse or physician endoscopy	No	No	Properly reported	Primary outcome parameter not related to endoscopic. Measured with Gastrointestinal Symptoms Rating scale up to one year after procedure	Only patients suitable to be serviced by nurse endoscopists included. Numerically more patients from the nurse cohort were lost of follow-up without specified reasons (286 *vs* 269). A trend for more patients with weight loss in the physicians cohort, more patients in the physicians'' cohort had previously barium enema (suggesting more chronic or relapsing symptoms)	Authors make reference to required sample sizes. Total number of patients completed was below the required sample size
Koornstra *et al*[11], 2009	It is stated that patients were randomly allocated, no information is given on allocation. Proportion of inpatients lower in the nurse group. No evidence for ethic approval or consent of patients. Training of nurse and medical staff was not identical	No	No	No information provided	Multiple endpoints reported	The authors developed a training program and with their data they aimed to confirm that their training program delivered (self-fulfilling prophecy).	Not powered to verify equivalence

Maslekar *et al*[31], 2010	Patients were allocated by administrative staff into the nurse or medical specialist group.	No	No	Incomplete response data cited as reason for exlusion (48/561 excluded), no intention to treat analysis	Study justifies an implemented service model that aims to address shortage of medical specialists	The instrument was unlikely to detect group differences. Variable mixture of flexible sigmoidoiscopy and colonoscopy across groups	No power calculation
Maslekar *et al*[32], 2010	No randomization	No information given	No	Not reported	Justifies implemented service and training model	For flexible sigmoidoscopies the validity of the endoscopists impression of maximal extension was tested. A priori unlikely to identify difference.	No power calculation
Shum *et al*[18], 2010	No randomizatiom, no comparator	No	No	No information provided	Justifies the implemented training model		No
Limoges-Gonzalez *et al*[44], 2011	It is stated that patients were randomly allocated, no information is given on allocation.	No	No	No information provided	Justifies the implemented service model	Postprocedure questionnaire was administered after (at least) 30 min of recovery. Drug effects likely to blunt potential differences	No power calculation
de Jonge *et al*[33], 2012	Routine quality data were used, no randomization.	No	No	No information provided	Data were partly retrospective data, partly prospective data, no justification given.	?	No power calculation
van Putten *et al*[34], 2012	Allocation of patients by secretatial staff, no randomization	No	Not reported	Not specified	Justifies and implemented service model	Significant differences in comorbidities (more severe in the Gastroenterologists group), differences in source of referral. Outcome assessment limited to immediate salary comparisons not total costs including pathology and follow-up.	No power calculation
Massl *et al*[5], 2013	It is stated that patients allocated by administrative staff, endoscopists assigned to lists randomly based on availability	No	No	79/2025 procedures not included due to drop out of 1 nurse endoscopist for unspecified reasons	Justifies the implemented service model	Patients younger than 18 years or referred for therapeutic procedures were excluded from the nurse endoscopist group only. Drop out of nurse endoscopist not justified.	Power calculation done. Appropriate numbers achieved.

Red cell = high risk of bias, yellow cell = unclear risk of bias, green cell = low risk of bias. CRC: Colorectal cancer.

costs being calculated as £53 per procedure in the non-physician group. They also found that patients who underwent a physician procedure had on average a greater gain of 0.0153 quality adjusted life years, based on responses from patient surveys. Their final conclusion was that at a price of £30,000 per QALY, the accepted NHS value, physicians were 87% more likely to be cost-effective 1 year after upper endoscopy or FS compared to nurse endoscopists.

DISCUSSION

The role of the nurse endoscopist initially arose to meet the burgeoning demand for endoscopies in the face of a severe shortage of physician endoscopists, first in the United States and later in the United Kingdom. To this day, the demand for endoscopic procedures continues to rise, due largely to the demographic changes associated with an ageing population[23,24] and the widespread introduction of colorectal cancer screening programs[25]. Additionally, it has been suggested that non-physician endoscopists could contribute to the much-needed provision of endoscopic services in the underserved rural and remote locations. Thus this systematic review was

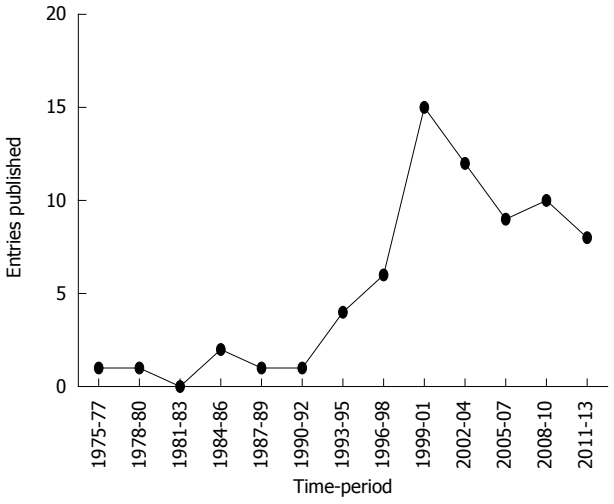

Figure 2 Number of peer reviewed publications since 1975. The number of publications peaked in 1991-2001 and continues to decline since that time.

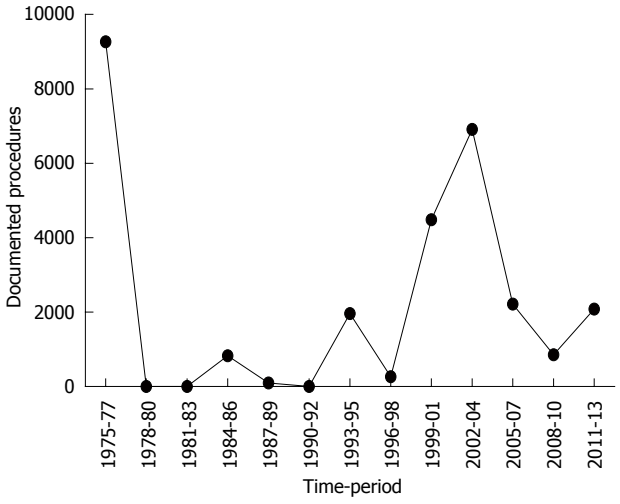

Figure 3 Number of procedures documented per 3 year time period.

conducted to assess the available evidence supporting the role of nurse endoscopists.

Our analysis suggests that under supervision by medical specialists non-physician endoscopists can perform GI endoscopy to a satisfactory standard; however this model of care does not seem to be cost efficient when compared with traditional physician service models. In addition, the studies have significant shortcomings and biases that limit their validity and generalizability. Most studies that addressed patient satisfaction and other endoscopic procedural (technical) competencies (for example, completion of procedure) were hampered by significant limitations such as lack of randomization, biased patient recruitment and allocation[4-9,11,12,16-18,22,26-34] and other methodological problems. With regard to potential general relevance of the available data, it must be noted that all studies were conducted in metropolitan centres. There are no data supporting safety and appropriateness of endoscopic services provided by non-medical endoscopists without close supervision outside of metropolitan centres. Thus, suggestions of improving endoscopic service provision at remote or rural sites by employing nurse endoscopists are unsubstantiated by any published data.

In this systematic review on non-physician endoscopy we ultimately identified 26 original datasets that were suitable for analysis. Of note, most studies were conducted prior to 2001 with a subsequent decline in total publication activity (Figure 2). Further, 96% of documented procedures performed by non-physician endoscopists in the past 3 years originated from two Dutch metropolitan tertiary centres. This apparent global decline in interest is supported by various surveys that show uptake of non-physician models is poorer than expected in the United States and United Kingdom, despite an increase in demand for endoscopies. Pathmakanthan *et al*[35] found that 42% of responding United Kingdom hospitals employed nurse endoscopists, and 90% of these were limited to esophagogastroduodenoscopies (EGDs) and FSs. However, the response rate to this survey was modest with 176 respondents from 292 (60%) surveyed hospitals. As a consequence, the results are likely to be subject to bias.

In the United States, Sharma *et al*[36] found that non-physician endoscopists performed 3.1% of EGDs, 2.2% of colonoscopies and 4% of FSs. Given that their response rate was only 2%, the true rate is likely to be much lower than this figure. The reason for the relatively limited uptake of nurse endoscopists remains unclear. However, considering that the nurse endoscopist's role was initially developed in the United States yet they perform only a small fraction of all endoscopies, it would appear that there are major flaws with the application of this service model. While reimbursement regulations may be the reason why nurse endoscopists are not contributing more substantially to service delivery, it appears that inferior cost-efficiency of nurse endoscopies is the reason for this minimal impact on service delivery.

From the data in Table 1, it is reasonable to conclude that there is evidence to support nurse endoscopists, and to a lesser extent, other non-physician endoscopists, in performing these procedures. However, there are clearly limitations. Nurses frequently had statistically significant shorter depths of insertion[7-10] but without effects on polyp or adenoma detection rates. Patient satisfaction, procedure times and complication rates were comparable when performed by physicians compared to non-physicians. It should be noted however, that complication rates of endoscopic procedures are low and are mostly related to interventions such as polypectomy. A recent large French study utilising a sample of approximately 100000 colonoscopies reported between 4.5 and 9.7 perforations per 10000 colonoscopies[37]. Complications rates for sigmoidoscopies are substantially lower[38,39]. With less than 18000 documented non-physician endoscopies

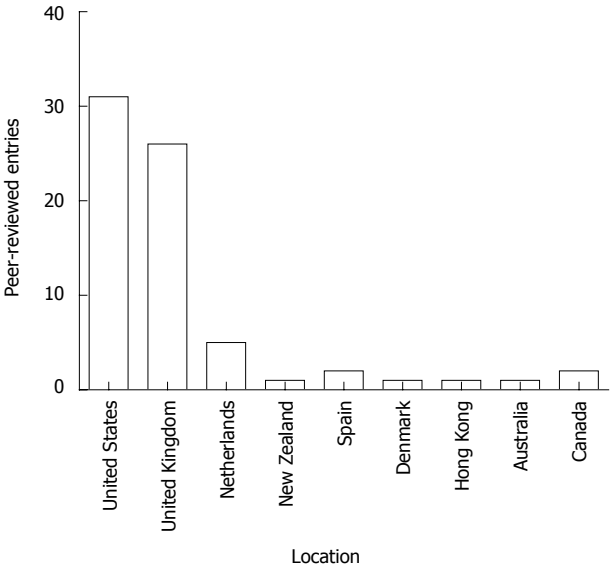

Figure 4 Geographic distribution of all publications reporting non-specialist endoscopies.

with safety data available and the majority of published studies focusing on low risk sigmoidoscopies, firm conclusions in relation to safety of endoscopic procedures done by nurse endoscopists cannot be made.

With regards to colorectal cancer prevention, colonoscopy is now the best endoscopic modality[40-43]. With regards to studies focussed on colonoscopies, there are two major Dutch studies. van Putten *et al*[34] found that nurse endoscopists could eventually reach an unassisted caecal intubation rate of 94%, however 23% of procedures still required a physician's assistance, 10 nurse endoscopists had an adenoma detection rate of 23%. There was 1 perforation from the 1000 procedures. The second Dutch study (Massl *et al*[5]) found that newly trained nurse endoscopists had a significantly lower caecal intubation rate compared to newly trained gastroenterology fellows (77% *vs* 88%, $P < 0.05$), yet procedure times and complication rates were similar. The smaller Dutch study found that nurse endoscopists and gastroenterology fellows/consultants had a similar overall caecal intubation rate, although levels of assistance were not documented[33]. The only recent non-Dutch study came from a University-based endoscopy clinic in the United States[44]. Their sole nurse endoscopist had an adenoma detection rate of 42%, *vs* 17% for 2 gastroenterology consultants. These findings were not replicated in any other colonoscopy or flexible colonoscopy study, which all demonstrated similar adenoma/polyp detection rates between non-physicians and physicians. Given the small number of patients and low number of proceduralists, this study is likely an outlier from the norm. Certainly, large trials in the United States have shown that adenoma detection rates in University-based endoscopy clinics can vary between 15.7% and 46.2%[45].

Providing endoscopic services is more than mastering the technical skills required to safely advance the scope. Lesion recognition in the context of the full clinical picture and decision making with regard to the overall management of the patient are critical components of patient care. There are no good data to support the performance of non-physician endoscopists with regard to these cognitive aspects of endoscopic procedures. If the detection of gross pathology could be perceived as a measure of cognitive competence, a study by Schroy *et al*[4] showed that nurse endoscopists performing sigmoidoscopies had a poor sensitivity (75%) while specificity (94%) was acceptable when compared with a consultant gastroenterologist's findings as the gold standard. Further evidence is required before non-physician endoscopists can be considered as being "competent" in endoscopy. Recognising relevant lesions and making clinical decisions in the context of the patient's full clinical picture is critical to deliver efficient and meaningful services.

Cost-benefit analyses are a way to assess the efficiency of services and genuine analyses on non-physician endoscopists are scarce in the literature. A crude cost-benefit analysis by Massl *et al*[5] suggests that a total saving of €7.61 per procedure could be achieved with a service model of three nurse endoscopists supervised by a gastroenterologist. However this did not account for differences in the costs of disease management including, follow-up procedures, follow-up consultations, expenditure for consumables and pathology. Indeed, nurse endoscopists take more biopsies than physicians (34.7% *vs* 26.5%, $P < 0.007$), with no additional detection of pathology[19]. Unsurprisingly, nurses had far greater levels of normal histology results than physicians ($P < 0.0001$)[19].

The sole genuine cost-benefit analysis in literature was a randomized study in the United Kingdom[19-21]. This study involved 30 nurse endoscopists performing both EGD and FS. Although the physicians' salaries were higher (£1.82/min *vs* £0.53/min), patients examined by nurse endoscopists had an increased need for subsequent endoscopies, specialist follow-up and primary care follow-up after the procedure. Thus the study concluded that at a price of £30000 per QALY, the accepted National Health Service value, physicians were more likely to be cost-effective one year after the procedure. This cost-benefit analysis did not take into account expenditure and loss of consultant time in training and supervising nurses, the increase in follow-up non-endoscopic investigations or increased expenditure for the required follow-up of biopsies. Based on the conservative estimates from the study, and the above mentioned additional unaccounted costs of nurse endoscopists, physician endoscopists appear to be more cost-effective than nurse endoscopists. While there is anecdotal evidence from individual sites that some nurse endoscopists

may work well in defined settings, the available data from larger studies does not support the assumption that the nurse endoscopy model is a more cost efficient service model.

While the salary of a nurse endoscopist might be lower as compared to a fully qualified specialist, it could be expected that services provided by nurse endoscopists are more cost efficient. However, the data point to the opposite. It is evident from the published data that the provision of endoscopic services is a multi-step process that includes a complex combination of patient-centred technical and non-technical cognitive skills. So far the assessment of endoscopic services delivered by nursing or other non-physician staff appears to be focussed on the technical aspects of procedures, rather than clinical gain of the procedures. This focus on technical/procedural aspects is appropriate to ensure safe service delivery. However, the implementation of nurse endoscopists to improve the delivery of endoscopy services is not cost-effective when compared with services delivered by specialists. This is most likely due to the cognitive aspects of service delivery. The comprehensive training of medical specialists appears to result in more cost effective service delivery.

When the model of nurse endoscopists was initially introduced in the United States and the United Kingdom the primary aim was to address the shortage of medical or surgical endoscopists. In most countries this is currently not the key problem; inappropriate funding, lack of infrastructure or issues of productivity and quality are the capacity limiting factors. Based upon the available evidence it is highly unlikely that the introduction or the increased use of nurse or other non-medical endoscopists will improve access to quality endoscopic services and improve the cost efficiency of delivery of endoscopic services.

Based upon the available anecdotal evidence and the data it appears that nurse endoscopists might be suitable to address shortages of workforce if they are imbedded into larger teams of specialists in metropolitan centres focusing on the delivery of less complex procedures such as follow-up surveillance procedures. However, before this is accepted as the appropriate setting for nurse endoscopists, the implications for training and overall productivity of services need to be properly explored, particularly in relation to colonoscopy and video capsule endoscopy where there are only limited reports on the use of non-physician endoscopists performing these procedures[46-50].

More data are obviously required. Besides the need to assess and improve the ability of nurse endoscopists to effectively contribute to the service delivery, it is necessary to explore all potential avenues that are suitable to provide cost efficient quality services to patients. This may include novel models of multi-professional teamwork, better integrated and focussed training of other professional groups such as General Practitioners for non-metropolitan (rural) settings to provide core endoscopic services to populations that are currently not properly serviced by specialists.

CONCLUSION

Most studies assessing training and performance of non-physician endoscopists have substantial methodological limitations. Studies were often uncontrolled, without random patient allocation and open to bias (selection and reporting bias). In all studies, nurse and other non-physician endoscopists worked only within a multidisciplinary team with strict supervision from a qualified physician or surgeon endoscopist.

With regard to cognitive competences in relation to the delivery of endoscopic services, nurses appear to perform less well than medical endoscopists. This emphasizes the need to work in teams with close supervision. In relation to cost-efficiency, nurse and non-physician endoscopists are probably less cost-effective than medical endoscopists. This is related to the increased need of follow-ups and reflects the cognitive component. More research is needed in this area.

All available data are from large and metropolitan centres. There is no evidence to suggest that the delivery of endoscopic services outside large metropolitan centres with several procedure rooms running in parallel benefits service delivery or is a safe option.

While nurse endoscopists may increase the capacity of endoscopic services when imbedded into larger endoscopic units, this does not appear to be a cost-efficient option as compared to traditional service models.

COMMENTS

Background

Nurse endoscopy training and delivery of endoscopic services was first reported in the United States more than 35 years ago for flexible sigmoidoscopy (FS). Several studies soon emerged, confirming that nursing staff with appropriate training and supervision could adequately perform endoscopic procedures such as FS. Other studies have since established that nurse endoscopists can safely perform upper endoscopies and colonoscopies. In an era where safe, yet cost-effective, policies run at the forefront of stakeholders' minds, the question of how nursing staff can undertake additional roles in the endoscopic suites is continually raised.

Research frontiers

There have been no systematic reviews of the literature that have examined the full body of evidence surrounding uptake, safety, accuracy and most importantly, the cost-effectiveness of nurse endoscopists.

Applications

Contrary to general beliefs, endoscopic services provided by nurse endoscopists are not more cost effective compared to standard service models and evidence suggests the opposite. Overall significant shortcomings and biases limit the validity and generalizability of studies that have explored safety and quality of services delivered by non-medical endoscopists.

Peer-review

The paper is very interesting with significant results in the field of evidence on safety, competency and cost-effectiveness of nursing staff providing gastrointestinal endoscopy services. The tables are too broad and difficult to clear. Authors need to reduce and make more informative.

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ISSN 1007-9327