

Revised Title

Interventions for maintaining nasogastric feeding after stroke: an integrative review of effectiveness and acceptability

Abstract

Aims and objectives

To investigate the effectiveness and acceptability of interventions for maintaining nasogastric tubes (NGT) in adult stroke patients.

Background

Internationally, incidence of Cerebral Vascular Disease (CVD) continues to increase and stroke is the largest cause of complex disability in adults. Dysphagia is common following a stroke which necessitates feeding via a NGT. NGT are not well tolerated by stroke patients and may be frequently dislodged. Hence, interventions such as tape, the nasal bridle/loop (NL) or hand mittens (HM) may be used to maintain NGT position. However, evidence around the effectiveness and acceptability of these interventions has not been reviewed and synthesised.

Design

Integrative literature review.

Method

Database searches in MEDLINE, PubMed, CINAHL, Scopus, Cochrane and EMBASE; manual reference list searches.

Results

Seven studies met the eligibility criteria and were included in the review. Evidence for the effectiveness of NL and HM to maintain NGT position in patients after a

stroke is sparse and methodologically poor, and especially limited around HM use.

There is insufficient evidence about the acceptability of both NL and HM among stroke patients.

Conclusion

Current clinical practice is underpinned by assumptions around the acceptability of NL and HM to secure NGTs. This results in reliance on consensual judgement between professional, patients and their families to guide their use among individuals with dysphagia after stroke. Further research is required to assess the effectiveness of HM and acceptability of both NL and HM among stroke patients to inform guideline development.

Relevance to Clinical Practice

Given the lack of evidence on the acceptability of HM and NL among stroke patients to inform evidence-based guidelines and protocols, healthcare professionals should reach consensus on their use by exercising clinical judgment and through consultation with patients (if possible) and their families.

Summary – What does this paper contribute to the wider global clinical community?

- Given the lack of evidence on the acceptability of HM and NL among stroke patients to inform evidence-based guidelines and protocols, healthcare professionals should reach consensus on their use by exercising clinical judgment and through consultation with patients (if possible) and their families.

- The use of HM and NL, which may restrict patients' freedom of choice, requires careful and comprehensive evaluation to identify risks and benefits.
- Application of HM and NL with vulnerable adults needs to be examined further in view of current legal and ethical principles in order to determine 'best interests'.

Keywords

Stroke; dysphagia; feeding; nasogastric tube; restraint; acceptability; nursing.; nasal loop; hand mittens

INTRODUCTION

Internationally, the incidence of Cerebral Vascular Disease (CVD) is increasing (World Health Organisation (WHO) (2014) and stroke is the largest cause of complex disability in adults (Stroke Association (SA) 2016). In the United Kingdom (UK), an estimated 152,000 people have a stroke each year, the majority of whom are over 65 years old (SA 2016). Malnutrition has been observed in 16-31% of stroke patients on hospital admission and affects almost 50% of stroke patients admitted to rehabilitation units (Geeganage et al. 2012; Nip et al. 2011). Dysphagia (i.e., an unsafe swallow) is common after stroke and has been reported in 28-67% of patients (Geeganage et al. 2012). To maintain feeding and prevent nutritional deterioration after stroke a percutaneous endoscopic gastrostomy (PEG) tube inserted directly into the stomach or nasogastric tube (NGT) inserted via the nose into the stomach, may be necessary (Dennis et al. 2006).

Research has shown that NGT are not well tolerated by stroke patients (Beavan et al. 2010). Patients may dislodge their tubes interrupting their nutrition, hydration

and/or medication, and increasing the risk of feed or fluid entering the lungs (Metheny & Meert, 2004). However the FOOD (Feed or Ordinary Diet) Trial (Dennis et al. 2006) indicated that NGT feeding in the acute stages after stroke (first 2-3 weeks) was more beneficial than PEG feeding. Therefore ensuring that NGT feeding is successfully maintained, can be an important element of successful rehabilitation. Common interventions used for maintaining NGT position in stroke patients include nasal bridle/loop (NL) and hand mittens (HM) (Gomes, Hookway & Weekes, 2014). However, both NL and HM are also classed as a form of restraint (Gomes, Hookway & Weekes, 2014; Gallagher 2011) and therefore their use poses considerable ethical dilemmas for both professionals in exercising their clinical judgement, and patients (or their families on their behalf) making decisions on whether and which method of restraint to use (Royal College of Nursing (RCN) 2008). Hence, to inform discussions and shared decision-making around their use between professionals, patients and their families the effectiveness and acceptability of their use needs to be determined.

Previous Systematic Review

Gomes, Hookway & Weekes (2014) carried out a systematic review on behalf of the Intercollegiate Stroke Working Party to inform the National Clinical Guidelines for Stroke (Royal College of Physicians (RCP), 2012). Their review sought to establish whether NL, HM or other restraint devices effectively maintain NGT position; reduce mortality and morbidity or prevent early PEG feeding for dysphagic stroke patients. Evidence from randomised controlled trials (RCT) was evaluated and one relevant RCT was identified (Beavan et al. 2010). This study indicated that the NL is effective at preventing NGT removal in stroke patients.

Following this systematic review, the National Clinical Guideline for Stroke, advised that NL or HM should be considered if NGT require frequent replacement (Gomes, Hookway & Weekes, 2014). This guideline also recommends that in areas where HM are used, locally agreed protocols should be in place to minimise complications (Gomes, Hookway & Weekes 2014). However, this and no previous review has examined the acceptability of using NL or HM when feeding stroke patients.

Aims

The aim of this integrative review was to investigate the effectiveness and acceptability of interventions for maintaining nasogastric tubes (NGT) in adult stroke patients.

METHODS

Literature published between 1980 and 2015 was searched. The selection of 1980 as the start date of the review was guided by knowledge that seminal papers related to NGT insertion and care were published at this time. Moreover, given the conclusions reached by the systematic review by Gomes et al (2014) – particularly about the paucity of research around acceptability of interventions – it was considered prudent to select a lengthy (25 year) time period.

The search strategy was developed after discussion with Cochrane Collaboration Stroke Group experts to find articles specifically related to NGT feeding and dysphagic stroke patients (Cochrane Collaboration, 2011). Combinations of the following search terms were used: stroke, cerebral vascular disorders, nutritional

support, enteral feeding, nasogastric feeding, and gastrointestinal intubation, **figure 1** illustrates the MEDLINE search performed.

Insert Figure 1 here

The following six electronic databases were searched: MEDLINE, PubMed, CINAHL, Scopus, Cochrane and EMBASE were performed. Following these database searches reference lists from relevant studies and reviews were reviewed.

Inclusion and exclusion criteria

Articles were included if they were: (1) written in English; (2) primary research studies (quantitative, qualitative or mixed method studies); (3) studies including adults of any age or sex with ischaemic or haemorrhagic stroke and dysphagia requiring NGT or naso-duodenal feeding for nutrition, hydration and/or medication; (4) studies that included some NGT fed dysphagic patients amongst patients with other medical conditions; (5) studies in stroke patients fed by other artificial or oral routes that include NGT or naso-duodenal feeding; (6) studies including patients in the acute phase of stroke (within 7 days of stroke onset), sub-acute phase (between 8 and 14 days of stroke onset) and the chronic phase (15 or more days after stroke onset) (Morten Rønning & Goldervog, 1998).

Papers were excluded if they were: (1) non-human; (2) non-English language; (3) single case studies; (4) studies in patients with subarachnoid haemorrhage (SAH), transient ischaemic attack (TIA) or dysphagia due to other medical conditions; (5) studies in stroke patients fed via other enteral routes; (6) expert opinion.

Search outcome

The PRISMA diagram in Figure 2 (PRISMA Group 2009) indicates the number of articles identified, screened and excluded during the review process. In summary, database searches identified 2868 records, of which 54 were identified as duplicates using the 'find duplicate' function in EndNote X7 (Clarivate Analytics, Toronto, 2016). Hand searching identified a further 3 records. Screening of titles and abstracts was conducted independently by two reviewers (CM, LV), with consensus reached through discussion on disagreements. Of the 2817 records screened, 2804 (97.7%) were excluded for reasons including: not addressing stroke and enteral nutrition, not addressing NGT feeding and stroke, not addressing dysphagia as a result of stroke (see Figure 2). Full-text screening of the remaining 13 articles was conducted by the first author (CM); all of which were then checked by the second author (LV). Following this initial sampling, no disagreements were identified and 7 further articles were excluded from the review for the following reasons: did not evaluate NGT feeding specifically or directly with stroke patients (n=3); did not specify the type of enteral feeding being evaluated (n=1); only addressed NGT dislodgement but not maintenance (n=1); did not address NGT feeding with standard tube; expert opinion (n=1) (Figure 2). A summary of articles that did not meet the eligibility criteria is provided in **table of supplementary information**.

[Insert Figure 2 and link to supplementary information]

Critical appraisal of selected studies

Critical appraisal of the included articles (n=6) was conducted using the most appropriate Critical Appraisal Skills Programme (CASP) checklist (CASP 2014).

Two authors independently evaluated the quality of each article, consensus being reached through discussion. Quality assessment of each of the included articles is shown in **Table 1**, and quality rating was determined using the Scottish Intercollegiate Guidelines Network (SIGN) grading system (2017) (**table 1**) and assigned to each study. Quality assessment was conducted to evaluate the available evidence-base; no studies were excluded from the review on the basis of this quality assessment.

[Insert Table 1 here]

Data extraction

Following critical appraisal, the following 6 variables were extracted from each article to inform integration of evidence across studies: (1) frequency and reason for NGT dislodgement; (2) length of time NGT remained in place with intervention; (3) percentage of prescribed feed/hydration delivered; (4) reasons for failure of NGT feeding with intervention in place; (5) complications associated with intervention used for securing NGT; (6) patient acceptability/tolerability of intervention and commencement of alternative feeding methods.

RESULTS

Table 2 provides details of the 6 studies included in the review, including the six variables extracted from each article. All the identified studies included dysphagic stroke patients who required NGT feeding; 3 studies were specific to dysphagic stroke patients (Beavan et al. 2010; Horsburgh et al. 2008; Anderson et al. 2004). All the studies examined methods for keeping NGT in place. Two studies solely evaluated the use of the NL (Beavan et al. 2010; Anderson et al. 2004), one study

looked at the use of HM only (Williams 2008). Horsburgh et al. (2008) evaluated HM and NL. The remaining two studies were less specific about the interventions applied to maintain NGT feeding (Quill 1989; Ciocon et al. 1988). Ciocon et al. (1988) refer to using HM and wrist restraints whereas Quill (1989) refers only to the use of restraint **(see Table 2)**.

[Insert Table 2 here.]

Effectiveness

Nasal Loop

Two studies have investigated the effectiveness of NL (Beavan et al 2010; Anderson et al 2004). Beavan et al. (2010) report significantly improved delivery of feed and fluid in the NL group ($p=0.002$), reduced electrolyte abnormality (31% vs 58%) compared to conventional feeding. Anderson et al. (2004) report that 57% ($n=8/14$) patients were successfully maintained on NGT feeding with a NL, with a 100% increase in feed delivery.

Beavan et al. (2010) report using fewer NGT in the NL group and fewer x-rays performed to confirm position. However, reasons for NGT dislodgement, which may be directly indicative of NL effectiveness, are not stated. Anderson et al. (2004) do not record the number of NGT inserted or dislodged pre or post NL; both studies do confirm that NGT removal with the NL in situ did occur. Beavan et al. (2010) report that both intervention and control group lost weight over the study duration. The differences between the two groups were minimal with the mean weight loss being

3kg (NL group 3.3kg; conventional NGT 2.9kg). Anderson et al. (2004) do not report on this aspect of NGT feeding with the NL.

Hand Mitten

One study has assessed the effectiveness of HM (Williams 2008). This study examined the use of mittens in a sample of (n=7) of which (n=4) were stroke patients who had previously dislodged more than two NGT's due to agitation. Two patients were able to give consent to wearing HM, for the remaining five participants assent was obtained from either family or consultant. Although indications for the use of hand mittens are recorded, their effectiveness were not ascertained.

Studies conducted by Ciocon et al. (1988) and Quill (1989) addressed HM but more specifically restraint. They did not add any further evidence about the effectiveness of HM with stroke patients, only that gastrostomy tubes were seen as better tolerated than NGT and negated the need for wrist restraints or hand mittens (Ciocon et al. 1988).

Acceptability

Nasal Loop

Three studies have assessed aspects of acceptability of NL (Horsburgh et al 2008, Beavan et al 2010, Anderson et al 2004). Beavan et al. (2010) observed adverse events associated with NGT feeding and although not deemed to be significant, the NL group experienced 37% (n=19/51) more nasal trauma compared to 15% (n=8/53) with conventional NGT feeding, specific details of 'trauma' are not provided, although no medical intervention was required. Anderson et al. (2004) report that 43%

(n=6/14) patients were able to communicate, 28% (n=4/14) of whom reported that the nasal loop was more acceptable than repeated tube insertion, one patient complained of associated nasal discomfort. Beavan et al. (2010) report that conventional feeding is more uncomfortable 41% (n=17/41) and the NGT more easily removed 27% (n=11/41) than NL feeding where 28% (n=12/43) reported discomfort and 16% (n=7/43) reported easy removal. However, these results were ascertained from a questionnaire given to participants and proxy respondents, the authors themselves state that during pilot testing, this questionnaire indicated poor validity, therefore necessitating focus groups with nurses to further represent perceptions about tolerability. Specific details of these focus groups are not reported in the findings, except that the authors state that nurses who participated associated greatest patient distress with the insertion or reinsertion of an NGT.

None of the patients interviewed in Horsburgh et al's (2008) study had experienced wearing NL, however patients were asked for their comments about the system after reading the product information. Concerns were expressed about the potential for pain and damage to the nasal septum if patients tried to remove the NGT.

Hand Mitten

Two studies examined the acceptability of HMs (Williams 2010; Horsburgh et al 2008). However, only Horsburgh et al. (2008) report on the experiences of a patient who had actually worn HMs. The patient described them as 'intrusive' and 'torture'. Both Williams (2010) and Horsburgh et al. (2008) offer further findings about the acceptability of HM from patients, family members, carers and staff who had no experience of wearing them. Opinions ranged between perceiving 'benefit' in avoiding repeated tube insertion to feelings of 'diminished autonomy and justice'

(Horsburgh et al. 2008). HM were also perceived as being 'too big and bulky', looking like 'boxing gloves' and 'looking comfortable'; one nurse related the 'shock of one patient while HM were being applied' (Williams 2010).

Although Ciocon et al. (1988) and Quill (1989) address HM and the use of restraint for maintaining NGT position, again they did not add any further evidence about their acceptability.

DISCUSSION

Few studies have assessed the effectiveness and acceptability of NL and HM and those that have are of relatively poor methodological quality (see table 1). Critical appraisal of existing evidence leads us to conclude that the effectiveness and acceptability of NL and HM has not been sufficiently established through research to fully justify their use in practice.

Beavan et al. (2010) and Anderson et al. (2004) propose that the NL effectively secures NGT's for stroke patients and assert that it is preferable to repeated NGT insertion. Beavan et al. (2010) demonstrate that NGT feeding with an NL improves enteral feed delivery. However, both the control and intervention groups suffered significant weight loss over a two week period. The acceptability of the NL is poorly addressed in both studies. Horsburgh et al. (2008) do address patient, staff and family perceptions about the NL and the overall theme attributed to this device was 'harm'.

On the basis of their findings, Beavan et al. (2010) recommend that reducing the number of NGT insertions is a justifiable rationale for NL feeding in stroke patients, the failure of which was seen as early insertion of a PEG tube or abandonment of enteral feeding; however the incidence of these outcomes is not clearly reported.

The use of HM for maintaining NGT position is examined by Horsburgh et al. (2008), Williams (2010), Ciocon et al. (1988) and Quill (1989). However, none of these studies adequately addresses effectiveness and only Horsburgh et al. (2008) begin to address patient perceptions of acceptability. Williams (2010) includes stroke patients with HM within the study sample, however it is only a small number of staff and family opinions that are reported in the findings; opinions are both positive and negative.

Mahoney et al. (2015) explore the opinions nurses working in stroke within the UK. A postal survey (RR=347) gauged perceptions about the acceptability and effectiveness of HM and NL. In their study HM were seen as the least safe and acceptable option for maintaining NGT position in stroke patients and the most acceptable option for this purpose was taping the NGT to the face (Mahoney et al 2015).

Most studies used a quantitative approach to measuring the effectiveness of NL, HM. However, within two of these studies qualitative insights are also reported (Beavan et al. 2010; Williams 2008). Beavan et al. (2010) describes carrying out focus groups with staff, but fails to follow up on these findings. Williams (2008)

interviews with carers and family but only report on the decision making process which lead to using HM, leaving the question of acceptability unanswered.

Only one study specifically adopted a solely qualitative approach to address issues of acceptability directly (Horsburgh et al. 2008). In this Grounded Theory study the perceptions of stroke patients, their family/carers and staff about HM and NL were explored. Their findings indicated that all participants identify that HM's reduce or diminish patient autonomy and that the NL may be perceived as painful and damaging. Horsburgh et al. (2008) conclude that the benefits of an intervention must outweigh potential harm and be justified in maintaining nutritional status. These findings concur with clauses in Adults with Incapacity (Scotland) Act (2000) and Mental Capacity Act (2005) that recommend that any intervention made in the care of an incapacitated adult must be deemed in their 'best interests'. The survey conducted by Mahoney et al. (2015) also sought to ascertain the views and experiences of nursing staff working within the specialty of stroke about the effectiveness, safety and acceptability of the NL. Their findings indicate that although nurses perceive the NL to be effective, they do not consider it to be safe or acceptable. Therefore, balanced against perceptions of 'harm', unacceptability, potential trauma and pain, current evidence does not satisfy the premise that the benefits of the NL outweigh its potential harms.

According to the Royal College of Nursing (RCN) (2008) restraint is *'the intentional restriction of a person's voluntary movement or behaviour'*. This definition can be applied to both HM and the NL. Laws covering the use of restraint come from criminal and civil law applicable to the UK, including the aforementioned Mental Capacity Act (2005) and Adults with Incapacity (Scotland) Act (2000). Whenever restraint is used, clear justification must be given in accordance with accepted professional standards (Nursing and Midwifery Council (NMC) 2015; RCN 2008). This integrative review demonstrates that justification for physical restraint of stroke patients requiring NGT feeding is not supported by sufficient evidence. Although recent guidance from the Royal College of Physicians (RCP) (Gomes, Hookway & Weekes 2012) acknowledges this in respect to HM, they do not advise against their use, but recommend that it is governed by local policy to minimise risk. The ethical and legal responsibility is therefore devolved to care settings and practitioners must reach consensus between themselves and with patients and/or their families prior to their use. Gomes, Hookway & Weekes (2012) also recommend that the NL is effective and should be considered for patients requiring repeated NGT insertion as these patients are often the most incapacitated following a stroke (Beavan et al. 2010).

In summary, current guidance does not report on potential harms or acceptability of NL and HM, which by their very nature, restrict freedom of choice and can result in potential physical and psychological harm (RCP 2012; Horsburgh et al. 2008). Moreover, there is currently insufficient evidence around the effectiveness and acceptability of alternative methods to NL and HM to maintain NGT position to inform clinical decision-making (Mahoney et al. 2015; Liu et al. 2013).

Conclusions

Evidence for the effectiveness of NL, HM and alternative methods to maintain NGT position in patients after a stroke is sparse and methodologically poor, and especially limited around HM use. Acceptability of all interventions used to maintain NGT feeding for stroke patients has not been adequately assessed and patient perceptions to date have mainly been sought by proxy (Mahoney et al. 2015; Beavan et al. 2010; Horsburgh et al. 2008). Further research examining the effectiveness and acceptability of NL, HM and alternative methods is required in order to ensure that patient experience and opinion informs the selection of appropriate intervention (Department of Health, 2010). Qualitative research to determine the risks and benefits of NL and HM for stroke patients is particularly warranted to inform development of local and national guidelines and protocols.

Relevance to Clinical Practice

The lack of evidence around the effectiveness and acceptability of NL and HM use among patients after a stroke, poses ethical dilemmas for professionals, patients and their families. This results in reliance on shared decision-making between professional, patients and their families around their use. This review recommends that in the absence of evidence and national clinical policies and protocols to guide this decision-making process, professional judgement should be exercised carefully and consensually informed by both the principals and spirit of the law. This requires the balancing of benefits and harms to ensure that the best interests of the stroke patient are upheld. Nurses and other healthcare professionals' involvement in research assessing the acceptability of interventions is warranted.

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