Abdominal massage for the treatment of constipation (Protocol)

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[Intervention Protocol]

Abdominal massage for the treatment of constipation

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ABSTRACT

This is the protocol for a review and there is no abstract. The objectives are as follows:

The primary objective is to assess the efficacy of abdominal massage for the treatment of constipation in adults.

BACKGROUND

Description of the condition

Patients with chronic constipation present with a number of symptoms including infrequent stools, excessive straining, hard stool, feeling of incomplete evacuation, abdominal pain and discomfort. The Rome III criteria, provide a framework for establishing a diagnosis of constipation (Longstreth 2006).

The Rome III criteria for functional constipation includes the presence of 2 or more of the following symptoms for at least 3 months:

- Straining in at least 25% defecations;
- Lumpy or hard stool in at least 25% defecations;
- Sensation of incomplete evacuation in at least 25% defecations;
- Sensation of anorectal obstruction / blockade in at least 25% defecations;
- Manual manoeuvres to facilitate at least 25% defecations (e.g. digital evacuation, pelvic floor support); and
- Fewer than 3 defecations per week.

Constipation is a prevalent condition that disproportionately affects women and older adults and can lead to self-medication and increased medical consultations. The prevalence of constipation in community-dwelling older people is estimated to be in the region of 20%, and the problem generates far in excess of 450,000 GP consultations per year in the UK at an estimated cost of more than £4.5M per year (RCGP 1995). Functional constipation, also known as chronic idiopathic constipation (CIC), does not have a physical (anatomical) or physiological (hormonal or other body chemistry) cause. It may have a neurological, psychological or psychosomatic cause. A person with CIC may be healthy, yet has difficulty defecating; their symptoms can often be attributed to slow transit or outlet obstruction (also known as pelvic floor dyssynergia). Constipation is commonly perceived to be a benign, easily treated condition with short-term treatment being relatively straightforward; however, chronic constipation is associated with mild complications that left untreated can develop into more serious bowel complaints (faecal impaction, incontinence and bowel perforations) with further implications for healthcare costs and the patient's health-related quality of life (HR-QOL). Existing evidence suggests that HR-QOL is lower in patients with constipation than in non-constipated individuals, and treatments for con-

stipation may improve HR-QOL (Mason 2002).

Description of the intervention

Abdominal massage for the management of constipation was used as early as 1870, reaching its peak in the late 19^{th} and early 20^{th} centuries. By 1950 it had all but disappeared. Abdominal massage was also part of the core curriculum for physiotherapy students for many years. However, massage has undergone a revival in clinical practice especially within the palliative care, oncology and hospice environments (Trevelyn 1996; Cole 1998). The massage is undertaken with the patient lying/semi lying in the supine position and involves manual massage over the area of the abdomen. Often there are several different techniques used within the sessions, some of which follow the anatomical route of the ascending and descending colon and others concentrate on sensory stimulation.

How the intervention might work

It is thought that by undertaking abdominal massage rectal loading is encouraged by increasing intra-abdominal pressure and in some cases it may elicit rectal waves which may stimulate the somato-autonomic reflex and enhance bowel sensation (Liu 2005).

Why it is important to do this review

It is important to undertake this review as no recent systematic review exists and there is growing interest in the use of massage within various populations. Abdominal massage may provide an important pragmatic approach to holistic bowel care. Numerous non-randomised studies of abdominal massage for CIC have published positive results, suggesting that abdominal massage may be an effective intervention for chronic constipation both for people with or without co-morbid conditions which may themselves exacerbate/cause chronic constipation. Potential biases such as selection, confounding and reporting bias, are likely to be higher with non-randomised studies. A systematic review is required to summarise the available data on the effectiveness of abdominal massage for the treatment of chronic constipation. The aim of this review is to answer the question: Does abdominal massage decrease physical or psychological morbidity and symptom distress and improve quality of life in patients with a diagnosis of CIC.

OBJECTIVES

The primary objective is to assess the efficacy of abdominal massage for the treatment of constipation in adults.

METHODS

Criteria for considering studies for this review

Types of studies

Randomised controlled trials and quasi-randomised trials will be considered for inclusion. Non randomised clinical trials will be excluded from the primary analysis, but will be evaluated in a sensitivity analysis

Types of participants

Patients, male or female, over the age of 18, with chronic constipation will be included. Included studies should provide a definition of chronic constipation and exclusion criteria should be clearly presented. Studies of patients with other diagnoses which may contribute to their diagnosis (e.g. Parkinson disease, multiple sclerosis, spinal cord injuries) will be included.

Types of interventions

Studies of abdominal massage therapy compared with the following control interventions: standard care, no treatment, laxative agents, biofeedback, transanal irrigation or any other non-surgical intervention will be considered for inclusion.

Types of outcome measures

Primary outcomes

The primary outcome measures will be global or clinical improvement as defined by the included studies (e.g. clinical symptoms including frequency of defecation, straining, lumpy or hard stools, sensation of incomplete evacuation, sensation of anorectal blockage, manual manoeuvres to facilitate defecation, pain, and bloating) and expressed as a percentage of the number of patients randomized (intention to treat analysis).

Secondary outcomes

The secondary outcome measures will include:

1. Frequency of defecation;
2. Type of stool;
3. Time spent on toilet;
4. Sensation of incomplete evacuation;
5. Manual maneuvers to facilitate defecation (e.g., digital evacuation, support of the pelvic floor);
6. Quality of life as measured by a validated index (e.g. SF-36);

7. Transit time measurement (radiopaque markers), functional rectoanal evaluation (proctoscopy, anorectal manometry, defecography, 0), or electromyography (EMG);
8. Cost effectiveness; and
9. Number and types of adverse effects.

Search methods for identification of studies

The following search strategy will be utilized for this review, using text and keyword/MESH terms for each database:
(abdominal massage) and (constipation) or (bowel dysfunction) or (faecal/fecal incontinence)
MESH/keyword terms will be modified as necessary for each database.

Electronic searches

Electronic searches
The following electronic databases will be searched with no restriction on language or publication status (e.g. in press articles): The Trials Registers of the Inflammatory Bowel Disease Group, the Cochrane Complementary Medicine Field, and the Cochrane Central Register of Controlled Trials (CENTRAL) on The Cochrane Library (2011), AMED (1985 to 2011), MEDLINE (1966 to 2011), EMBASE (1980 to 2011), Cinahl (1982 to 2011), and the British Nursing Index (1984 to 2011). Conference proceedings including Digestive Disease Week (DDW 2011), and the United European Gastronenterology Week (UEGW 2011), and the Conference Proceedings Citation Index - Social Science and Humanities (CPCI-SSH) (2011) will be searched to identify studies published in abstract form.

Searching other resources

The reference lists of identified randomised clinical trials and review articles will be checked in order to find randomised trials not identified by the electronic searches. Ongoing trials will be searched through the national research register and the website www.controlled-trials.com and the grey literature through the SIGLE database. Other unpublished studies will be identified through searches of conference proceedings as identified above.

Data collection and analysis

Selection of studies

Two authors (DM & LD) will independently review the abstracts of potentially relevant studies to determine if they meet the prespecified inclusion criteria and full publications will be obtained where necessary. Any disagreement between authors will be resolved by consensus and if necessary by consultation with the third author (SH). Full publications will be obtained for all eligible studies.

Data extraction and management

A standardised data extraction sheet will be developed to record data on: study quality, study setting, participants (age and sex; how diagnosis was confirmed; inclusion and exclusion criteria), interventions (description of massage, administration, duration, regimen of control intervention) outcome measures, attrition, intention to treat analysis, duration of follow-up and the type and number of any reported adverse events.The methodological quality of each study will be assessed and where necessary the study authors will be contacted for missing data or clarification of the published data. .

Assessment of risk of bias in included studies

The Cochrane risk of bias tool (Higgins 2008) will be used to asses the quality of randomised controlled trials. Factors to be assessed include:
sequence generation;
allocation sequence concealment;
blinding;
incomplete outcome data;
selective outcome reporting; and
other potential sources of bias.
Items will be rated as low risk of bias, high risk of bias, or unclear (or unknown) risk of bias. Disagreements will be resolved by consensus between DM and LD. Study authors will be contacted when insufficient information was provided to determine the risk of bias.

Measures of treatment effect

The relative risk (RR) with 95% confidence intervals (95% CI) will be calculated for each dichotomous outcome. The number needed to treat (NNT) and risk difference (RD) will be calculated where appropriate. For continuous variables, the weighted mean difference (WMD) or standardised mean difference (SMD) with 95% CI will be calculated.

Unit of analysis issues

The analysis will take into account the level at which randomisation occurred. In most cases the number of observations in the analyses will match up the number of 'units' (participants) that were randomised. For a parallel group design a single measurement for each outcome from each participant will be collected and analysed. We will also consider if groups of individuals were randomised together to the same intervention (cluster randomisation), or if individuals undergo more than one intervention (i.e.

cross-over trial) or if there are multiple observations for the same outcome.

Dealing with missing data

Where data are incomplete the last value will be carried forward

Assessment of heterogeneity

Heterogeneity will be assessed using the chi-square test (a P value of 0.10 will be regarded as statistically significant). The I^2 statistic will be used to estimate the degree of heterogeneity. This measure describes the percentage of total variation across studies that results from heterogeneity rather than chance. A value of 25% is considered to indicate low heterogeneity, 50% moderate heterogeneity and 75% high heterogeneity (Higgins 2003). Sources of heterogeneity will be investigated using a graphic display. The log RR and its 95% CI will be calculated and plotted for each trial. These plots will be examined to identify any possible outliers as well as to explore any trends in outcome due to differences in methodology, patient population or treatment regimens.

Assessment of reporting biases

Potential publication bias will be investigated using the funnel plot or other corrective analytical methods (Egger 1997). A linear regression approach to measure funnel plot asymmetry or the natural logarithm scale of the odds ratio will be used.

Data synthesis

Data will be analysed using Review Manager (revMan 5.0.25). Data from individual trials will be combined for meta-analysis if the interventions, patient groups and outcomes are sufficiently similar (to be determined by consensus). Data will not be pooled for meta-analysis if a high degree of heterogeneity is detected i.e. (I^2 > 75%). A fixed effects model will be used to pool data in the absence of heterogeneity. A random effects model will be used if significant heterogeneity is detected. The pooled RR and 95% CI will be calculated for dichotomous outcomes. For continuous outcomes the pooled WMD or SMD and 95% CI will be calculated as appropriate.

Subgroup analysis and investigation of heterogeneity

If sufficient number of randomised trials are identified, the following subgroup analyses will be performed:
1. Duration of disease (less than 5 years, 5-10 years, more than 10 years);
2. Existence of conditions such as MS, PD diabetes, spinal cord injuries; and
3. Delivery of the intervention.

Sensitivity analysis

A sensitivity analysis will be carried out to determine if the findings from the primary analysis are changed by incorporating different trials in the analysis (e.g. non randomised clinical trials). This will be done by varying the inclusion criteria and repeating the analysis with the new data set. If a sufficient number of randomised trials are identified, a sensitivity analysis to explore the influence of trial quality on effect estimates will be performed.

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* *Indicates the major publication for the study*

HISTORY

Protocol first published: Issue 4, 2011

CONTRIBUTIONS OF AUTHORS

DM initiated, designed the study and drafted the protocol. DM and LD will extract the data and conduct quality assessment

SH will supervise the statistical analysis, comment on and revise the protocol and will check the data extraction and arbitrate

DECLARATIONS OF INTEREST

DM, and SH have designed and conducted a RCT comparing abdominal massage for constipation in people with multiple sclerosis (Funded by MS Trust)

DM and SH have designed and are undertaking a RCT comparing abdominal massage for constipation in people with Parkinsons disease (Funded by the Parkinson's Society). LD has worked as a RA on this project part-time.

SOURCES OF SUPPORT

Internal sources

- Chief Scientist's Office, Scotland, UK.

External sources

- No sources of support supplied