

Are we following an algorithm for managing chronic anal fissure? A completed audit cycle[☆]



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HIGHLIGHTS

- A retrospective audit regarding management of chronic anal fissure (CAF).
- Adherence to ACPGBI standards reduces the need for potentially unnecessary surgery.
- Conservative management of CAF provides an effective treatment strategy.
- Following change, re-audit demonstrated significant improvement in management of CAF.

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ABSTRACT

Background: Anal fissure is one of the commonest proctological diseases with considerable national variation in sequential treatment. We aimed to audit our compliance of chronic anal fissure (CAF) management with national guidance provided by the Association of Coloproctology of Great Britain and Ireland (ACPGBI).

Methods: We retrospectively audited patients presenting to outpatient clinics with CAF over a 6-month period. Using electronic patient records, notes and clinic letters, we compared their management with ACPGBI algorithm. A prospective re-audit was then performed.

Results: Forty-one patients were included in the analysis (59% male). Sixty-eight percent ($n = 28/41$) of patients were appropriately started on conservative dietary therapy, of whom only 7.1% ($n = 2/28$) had treatment success. Eighty-nine percent ($n = 25/28$) were then appropriately treated with either topical diltiazem 2% or GTN 0.4%. Overall, 43.9% ($n = 18/41$) of all patients' entire management strategy adhered to the ACPGBI guidelines. In total, 48.8% ($n = 20/41$) patients had surgical treatment (excluding Botox), of which only 15% ($n = 3/20$) had undergone ACPGBI-compliant management. After local dissemination of results and education, the re-audit of 20 patients showed significant improvement in adherence to the guidelines (43.9% vs. 95%; $P = 0.0001$).

Conclusions: Topical creams were the most successful treatments (50%; $n = 9/18$) in ACPGBI-compliant strategies. Importantly, these data suggests that compliance with the ACPGBI algorithm leads to healing without surgery in 83.3% ($n = 15/18$) of patients, compared to 26.1% ($n = 6/23$) with non-compliant methods ($P = 0.0004$). This highlights the benefit of early conservative and medical management of CAF, before attempting surgery.

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1. Introduction

Chronic fissure-in-ano is a proctological condition often ignored or misdiagnosed by clinicians, both in the community and by junior doctors in colorectal surgical clinics [1]. Simple measures have been shown to be effective in treating the condition thereby avoiding surgery [2]. Often, managing benign proctology conditions can be more challenging than the complex cancer cases.

An anal fissure is a linear ulcer of the squamous epithelium within the anal canal distal to the dentate line. Anal fissures are common, with an incidence of 1 in 350 and a lifetime incidence of up to 11.1% [3]. Fissures most commonly present in the 2–4th decades with an equal propensity between sexes. The majority of fissures are sited posteriorly (90%), and present with pain on defecation and/or per rectal bleeding, due to hypertonia of the internal anal sphincter, resulting in ischemia [4].

A number of management strategies are used to treat chronic anal fissure (CAF) focussing on the reduction of anal tone [5]. Initial treatment is centred on conservative management with general measures, such as topical analgesics, increasing dietary fibre, laxatives and maintaining appropriate fluid intake. Medical management utilises topical glyceryl trinitrate (GTN) 0.4% and diltiazem 2% creams, whilst Botulinum toxin (Botox) has also been shown to be effective [6]. Surgical treatment is often necessary if conservative and medical managements are ineffective [7]. A variety of procedures are employed including lateral sphincterotomy, fissurectomy and anal advancement flap.

There is considerable national variation in the sequential treatment of CAF [8]. Management strategies have been provided as national guidance by the ACPGBI [9] in 2008 (Fig. 1). The ACPGBI position statement is based on Level 1, Grade “A” evidence.

2. Aims

To review the management of CAF within our two hospitals in accordance to the ACPGBI guidelines.

3. Methods

Patients were identified with CAF through a database search using clinical coding and ICD-10 codes over a 6-month period (February–July 2014). Electronic patient records, notes and clinic

letters were assessed retrospectively. Basic demographic information was collected using a proforma along with treatment strategies employed in patient care. Comparison was then made to the standards of care recommended in the ACPGBI guidelines (Fig. 1). Consecutive patients from January 2015 onwards were identified in the same manner.

4. Standards

Six key standards were highlighted to assess management within our two hospitals against the ACPGBI statement (Table 1).

5. Results

5.1. Initial audit

There were 534 patients identified using ICD-10 codes between February and July 2014, of which 41 patients (17 females, 24 males) with CAF were included. Of these, 31 were seen in colorectal clinic, 8 in general surgical clinic and 2 in gastroenterology clinic.

Compliance and non-compliance to the ACPGBI management algorithm is demonstrated in Table 2 and via flow diagram in Fig. 2. Conservative therapy was initiated appropriately in 28 patients, with 13 patients not receiving these simple measures. Of the 28 patients, 2 were treated successfully, whilst 1 was inappropriately administered Botox without having a trial of topical creams. Topical GTN 0.4% and Diltiazem 2% creams were correctly prescribed for the 25 patients compliant with the algorithm, successfully treating 9 patients. Eight patients were non-compliant with the algorithm and underwent surgical intervention before further non-surgical management (i.e. Botox). The procedures performed were lateral sphincterotomy (n = 5), creation of anal advancement flap (n = 1), anal dilatation (n = 1), and fissurectomy (n = 1).

The remaining 8 patients compliant with the algorithm were given Botox, of which 4 were treated successfully, 3 went on to have appropriate surgical intervention and 1 patient was treated inappropriately with anal dilatation.

Overall, 43.9% (n = 18/41) of all patients' entire management strategy adhered to the ACPGBI guidelines. Topical diltiazem/GTN was the most successful treatment in ACPGBI-compliant strategies, leading to success in 50% (n = 9/18). In total, 20 patients had surgical treatment (excluding Botox), of which only 35% (n = 7/20) had undergone ACPGBI-compliant management. Compliance with the ACPGBI management guidelines leads to treatment success without surgery in 83.3% (n = 15/18) of patients, compared to 26.1% (n = 6/23) with non-compliant methods (Fisher's exact test P = 0.0004).

5.2. Implementation of change

Results from the initial audit were presented locally to the department of general surgery. This presentation also included a detailed overview regarding the ACPGBI management guidelines.

5.3. Re-audit

A re-audit was carried out to assess whether practice within our trust had changed. Having completed and presented our initial audit in December 2014 we identified and analysed the next 20 patients with CAF from 01/01/2015 to 31/03/2015. The same methodology used in the initial study was applied to the re-audit.

The results of the re-audit are presented in Table 2 and in the flow diagram in Fig. 3. Of the 20 patients analysed, 19 were seen in colorectal clinic and 1 in a general surgical clinic. The male to female ratio was 12:8. Conservative management was initiated in 100% of patients (n = 20/20). Topical diltiazem or GTN was

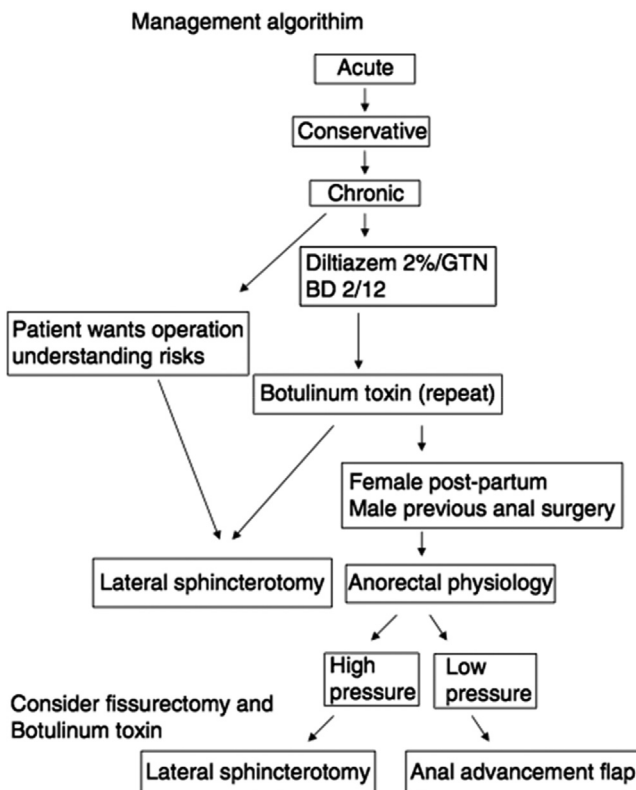


Fig. 1. ACPGBI management algorithm.

Table 1
Study standards.

Standards	Target	Source of evidence
Appropriate initiation of conservative therapy	100%	ACPGBI Position Statement (2008)
Appropriate initiation of topical GTN 0.4% or diltiazem 2% for 8 weeks	100%	ACPGBI Position Statement (2008)
Appropriate application of Botulinum toxin 20–25u after failed medical therapy	100%	ACPGBI Position Statement (2008)
Appropriate surgical management with either lateral sphincterotomy, fissurectomy or anal advancement flap	100%	ACPGBI Position Statement (2008)
Overall adherence to ACPGBI management algorithm	100%	ACPGBI Position Statement (2008)
Information leaflet given to patient (documented)	>80%	Locally agreed

Table 2
Results of the completed audit cycle and comparison to standards.

Standards	Target	Audit achieved	Re-audit achieved	Audit vs. Re-audit P value (Fisher's exact)
Appropriate initiation of conservative therapy	100%	68.3% (28/41)	100% (20/20)	<u>0.0056</u>
Appropriate initiation of topical GTN 0.4% or diltiazem 2% for 8 weeks	100%	64.1% (25/39)	100% (19/19)	<u>0.0023</u>
Appropriate application of Botulinum toxin 20–25u after failed medical therapy	100%	30.8% (8/26)	80% (4/5)	0.0600
Appropriate surgical management with either lateral sphincterotomy, fissurectomy or anal advancement flap	100%	15% (3/20)	50% (1/2)	0.3377
Overall adherence to ACPGBI management algorithm	100%	43.9% (18/41)	95% (19/20)	<u>0.0001</u>
Information leaflet given to patient (documented)	>80%	12.2% (5/41)	85% (17/20)	<u>0.0001</u>

Underlined values are statistically significant.

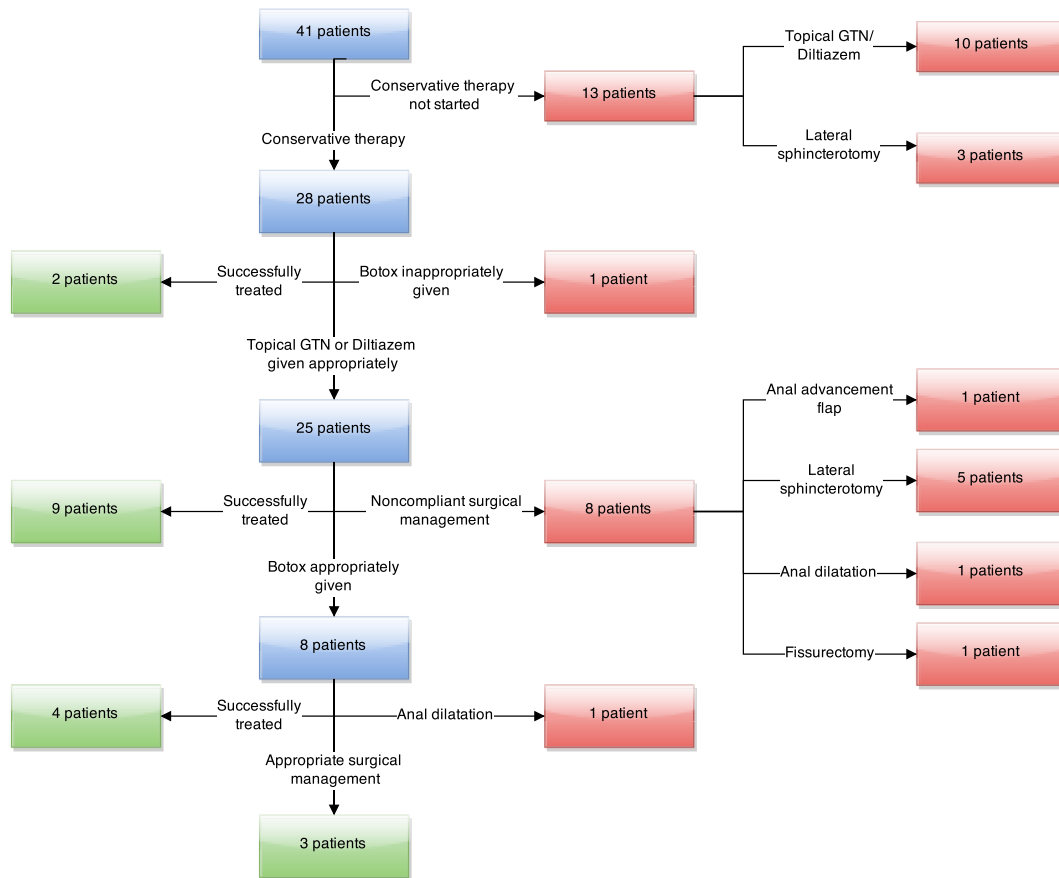


Fig. 2. Compliance/non-compliance to the ACPGBI management algorithm: Initial Audit.

appropriately trialed following conservative management in 100% of patients (n = 19/19). Four out of five patients within the re-audit underwent appropriate injection of Botox in accordance with the guidelines. The patient that underwent appropriate surgical management had a lateral sphincterotomy following failure of conservative and Botox therapies. One patient's management was not compliant with the protocol, undergoing lateral sphincterotomy

without utilising Botox treatment. Overall compliance with the ACPGBI guideline in the re-audit was 95% (n = 19/20). This was a significant improvement from the initial audit (43.9% vs. 95%; P = 0.0001). An information leaflet was given to 85% of patients (n = 17/20).

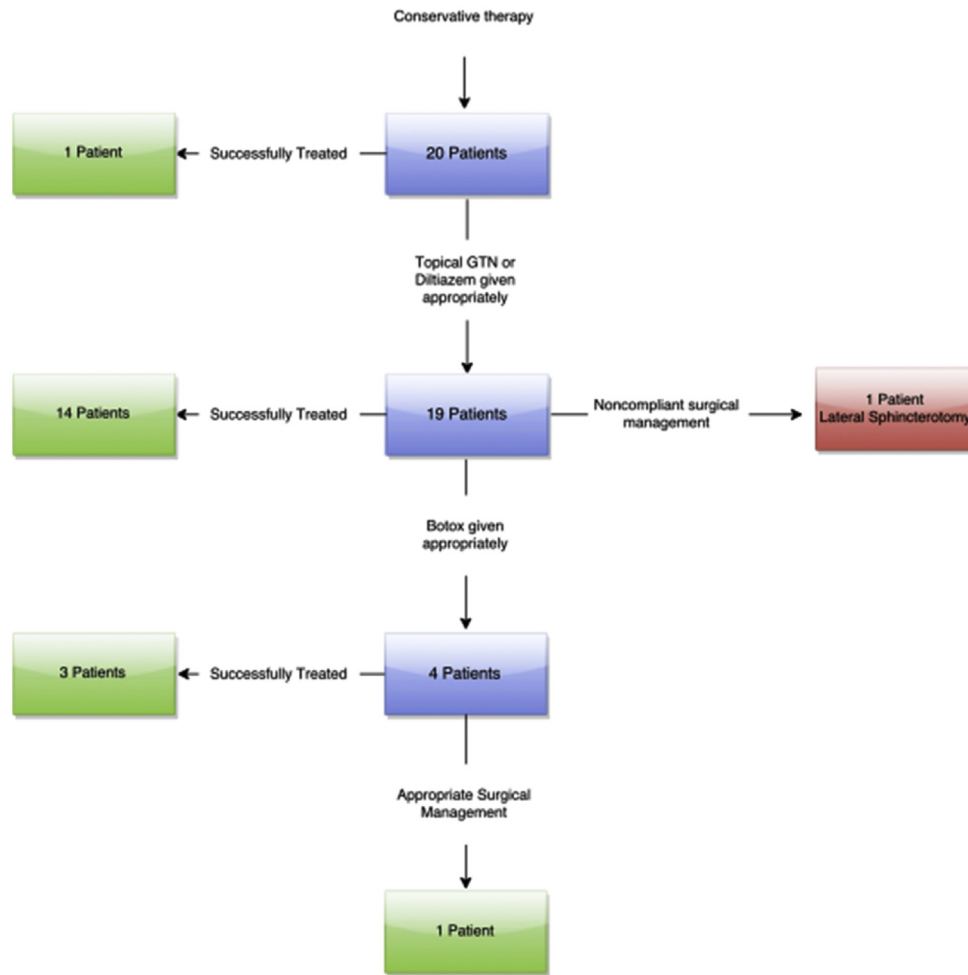


Fig. 3. Compliance/non-compliance to the ACPGBI management algorithm: Re-Audit.

6. Discussion

Our study highlights a number of key points that relate to the management of CAF within our two hospitals. We deemed compliance with the ACPGBI guidelines as following the algorithm step-by-step and initiating appropriate management strategies when other treatments had failed.

In the initial audit, conservative management was initiated in 68.3% ($n = 28/41$) of patients as first line treatment for CAF, whilst in the non-compliant ACPGBI arm 13 patients did not receive appropriate management. Two patients were successfully treated with conservative therapy alone. These figures represent poor compliance with the guideline. A variety of factors may account for these findings. Firstly, the data was collected retrospectively. Consequently, the documented management may have differed considerably from the management given, particularly with regard to conservative treatment, which includes dietary advice to avoid constipation and straining. Such measures are often initiated in primary care prior to specialist input and are mandatory. Equally, the quality and detail of documentation varied markedly between patients making it difficult to determine what, if any, prior treatments patients had received.

Patients with previous CAF that were successfully treated were difficult to place within the algorithm. We defined treatment success for our study as resolution of symptoms and discharge from surgical clinic. Thus, in those patients with a recurring fissure, if

their symptoms had completely resolved they were treated as a new presentation.

Just 64.1% ($n = 25/39$) of patients were appropriately treated with GTN or diltiazem creams in compliance with the algorithm. This result again is difficult to interpret in its' entirety given the retrospective nature of the study. Four patients in the non-compliant strand were not commenced on topical GTN/diltiazem advancing straight to lateral sphincterotomy. The algorithm states that patients with CAF can proceed to surgery (i.e. lateral sphincterotomy) without undertaking further conservative steps if they prefer and understand the operative risks. However, we found no evidence of any patient actively requesting surgery.

The target of 100% appropriate application of Botox 20–25 i.u. after failed medical therapy was not met in our initial study with only 50% ($n = 8/16$) utilising this procedure. Of the 8 patients given Botox appropriately in the ACPGBI compliant strand following failed medical therapy, there was a 50% treatment success rate. This is consistent with previous studies (43–49% success rate) [10,11]. Long-term success following Botox is still questionable with one study reporting a higher incidence of recurrence when compared to patients undergoing lateral sphincterotomy [7].

In those patients that did not receive conservative treatment initially ($n = 13$), 4 patients continued directly to lateral sphincterotomy, whilst 8 of the 9 patients that failed medical therapy were not commenced with Botox despite being suitable. The poor compliance with administering Botox highlights an area for

improvement within our unit, as this is evidently being under-utilised. Specific reasons are unclear, however, discrepancies in up to date clinical knowledge and practice within our centre may account for this.

Fifteen percent ($n = 3/20$) of patients had appropriate surgical management with lateral sphincterotomy, fissurectomy or anal advancement flap following failure with conservative and medical treatment. Whereas those patients that underwent surgical procedures (i.e. 4 anal dilatations, 7 lateral sphincterotomies, 1 fissurectomy, 1 anal advancement flap) without complete or appropriate conservative/medical work-up represent the non-compliant strand. The results demonstrate that within our centre, surgical management appears to be over-utilised currently. Surgery has a variety of potential complications, not least anal incontinence meaning that some patients may be exposed to risks unnecessarily (see [Table 3](#)).

Importantly, this study gives an over-view of the treatment of CAF in our centre and not details on single cases, meaning that we cannot comment on individual patient management. Case specific factors may have influenced surgical management decisions (e.g. length of symptoms, previous fissure-in-ano, patient wishes and comorbidities).

A variety of surgical procedures were performed with lateral sphincterotomy being the most commonly performed. This is recommended practice as outlined by ACPGBI when other non-invasive managements have failed. Four anal dilatation operations were performed over the time period. However, evidence does not support this practice due to a lower healing rate and a higher risk of incontinence compared to lateral sphincterotomy [12]. One fissurectomy and one anal advancement flap were performed. These operations whilst appropriate tend to be used in more specific cases as outlined within the algorithm.

Within our cohort there were no post-partum patients, although 7 males with previous anal surgery were included (i.e. 3 haemorrhoidectomy, 2 lateral sphincterotomy, 1 anal dilatation, 1 unknown). Of these, only 1 went on to have further surgery (lateral sphincterotomy), but he did not have preceding anorectal physiology. Due to the size of our study we were unable to adequately assess our centres' management of such patients. These patients require greater pre-operative work up with anorectal physiology helping direct surgical intervention.

The majority of patients with CAF were seen in colorectal clinic (75%). Given the high incidence of the condition and the potential need for surgery and associated complications, specialist input should be sought. Five of 41 patients received an information leaflet on CAF denoting a 12.2% achievement rate, as opposed to our target of >80%. Leaflets are not always available; however this highlights an area of inadequacy. Addressing this aspect will enable our patients to be more informed and play a greater role in managing their own condition.

Compliance with the ACPGBI management algorithm leads to treatment success without surgery in 83.3% ($n = 15/18$) of patients, compared to 26.1% ($n = 6/23$) with non-compliant methods (Fisher's exact test $P = 0.0004$). Overall, 43.9% ($n = 18/41$) of all patients' entire management strategy adhered to the ACPGBI guidelines. Topical diltiazem/GTN was the most successful

treatment in ACPGBI-compliant strategies, leading to success in 50% ($n = 9/18$).

The introduction of simple measures such as laminated algorithms in colorectal clinics, presenting the results of the initial study within our department and raising awareness of appropriate management has led to striking improvements. The results of our re-audit demonstrate our centre's compliance with the ACPGBI algorithm has significantly improved from an overall rate of 43.9%–95% ($P = 0.0001$). The re-audit revealed that compliance across all 6 standards being measured had increased. Conservative management with conservative therapy/laxatives and GTN/diltiazem creams was appropriately administered to 100% of patients in comparison to 68% ($P = 0.0056$) and 64% ($P = 0.0023$) in the initial study respectively.

There have been no directly comparable studies looking at a centre's compliance with a guideline such as the ACPGBI one. There is a large quantity of evidence related to the management of CAF of which our results are able to contribute to. Sinha et al. conducted a similar study investigating compliance with another algorithm in the management of CAF; findings revealed that the majority of patients responded to conservative management with only 26.3% of all patients requiring surgery [13]. Interestingly, Samin et al. reported no significant difference between diltiazem and Botox in healing CAF [10]. Arroyo et al. report healing rates of 92.5% in patients undergoing lateral sphincterotomy compared to 45% in patients treated with Botox alone. However a 5% rate of anal incontinence is associated with the procedure [7]. A randomised prospective controlled trial by Valizadeh et al. compared Botox injection and lateral sphincterotomy revealing a higher rate of recurrence with Botox and faster recovery with lateral sphincterotomy, although rates of faecal incontinence were significantly higher with surgical intervention [14]. Brown et al. also carried out a similar study comparing lateral sphincterotomy with the use of GTN following up their patient cohort over 6 years [15]. Their results support a higher healing rate with surgical intervention, but no long term difference in incontinence rates [15]. The systemic review by Garg et al. [16] adds further evidence to the risks of lateral sphincterotomy stating “the long-term risk of continence disturbance after lateral internal sphincterotomy is significant” and is estimated at 14%.

6.1. Limitations/Strengths

The study has a number of limitations. The data was collected retrospectively and as a result the management documented may have differed considerably from that given, particularly with regards to conservative treatment. The quality and detail of documentation varied markedly making it difficult to determine what management patients had prior to specialist referral. Consequently more patients have been compliant with the algorithm than identified.

A further limitation relates to the study size. Forty-one patients were included over the 6-month period from our two district general hospitals; hence, the significance of the results needs to be contextualised. A larger cohort may offer greater significance to the findings, but equally may highlight further limitations in

Table 3
Review of complication rates associated with treating chronic anal fissures.

Snor	Lateral sphincterotomy	Fissurectomy	Anal advancement flap	Anal dilatation
Pain	8% [17]	–	4% [17]	–
Failure to heal	2–7.5% [7,18]	11.6% [19]	6–8% [20,21]	Up to 56.5% [22–24]
Incontinence	0–14% [16,18,23]	7% [26]	0% [25]	12.5–39% [22,24]

documentation.

A strength of the study relates to the prospective re-audit that demonstrated a significant improvement in compliance and patient care. It also highlighted areas of underutilisation (i.e. Botox injection) and instances of outdated practice (e.g. anal dilatation).

6.2. Recommendations

The study highlighted a number of areas of improvement to adapt current practice within our centre. We suggest:

- Avoidance of therapies with poor evidence (i.e. anal dilatation)
- Increasing trainee awareness and implementation of educational sessions highlighting the benefit of compliance with ACPGBI algorithm
- Reinforcing the importance of conservative and medical management for appropriate duration
- Clearer documentation of management in clinical notes will aid other clinicians in determining where a patient lies with regard to the algorithm
- Introduction of laminated ACPGBI algorithm in each general surgery/colorectal clinic room to act as a visual aid memoire.
- Ensuring patient information leaflets are readily available in clinic rooms.

Following implementation of these recommendations within our centre, a further and larger re-audit will be carried out to monitor adherence to the ACPGBI guideline.

7. Conclusions

The study highlights that treatment varied considerably within our centre with poor compliance against the ACPGBI standards. Adherence to ACPGBI standards reduces the need for potentially unnecessary surgical management. Initiation of appropriate conservative and medical management of CAF appears the most effective treatment strategy, whilst botulinum injection may be being underutilised within our centre. There are also cost implications with conservative management providing a significant reduction in patient costs, without loss of effectiveness.

Although there are limitations to this audit, the general trends reinforce current evidence that conservative management of CAF provides an effective treatment strategy, helping minimise the need for invasive surgery. Optimum compliance with the ACPGBI guideline should not be understated. The findings from this single centre study may be extrapolated to other centres to help improve patient care.

Ethical approval

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Author contribution

Study design: AEF; KS, NF.
Data collection: NF, KS, JB.
Data analysis: AEF, KS, NF, JB.
Writing: NF, KS, AEF, AG.
Supervision: AEF, AG, NJW.

Conflict of interest

None.

Consent

None.

Registration of research studies

Researchregistry673.

Guarantor

Adam Frampton.

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