



## EASTERN PELVIC FLOOR SOCIETY

### Minutes

#### Eastern Pelvic Floor Society Meeting, Wednesday 20<sup>th</sup> April, 2016 Pontlands Park, Chelmsford

**Chair:** Subash Vasudevan

**Attendees:** Subash Vasudevan (Colchester, group chair), Ami Mishra (West Suffolk, group secretary), Lindsay Wheatley (Colchester), Graeme Smye (Broomfield), BV Praveen (Southend University), Ali Malik (Ipswich), Alison Wright (Aspire Pharma), Paula Hughes (EES), Chandima Halahakoon (Colchester), Vikas Kumar (Southend University),

**Apologies:** Abraham Ayantunde (Southend University), Samantha Head (Colchester), Darren Boone (Colchester), Shamim Haider (Colchester), Shahab Siddiqi (Broomfield)

#### 1. Minutes 13.01.2016

- The minutes from the previous meeting were agreed upon.

#### 2. Pelvic floor physiotherapy at Colchester

Lindsay Wheatley gave a presentation on the services provided by the physiotherapy department at Colchester.

Main points

- Different biofeedback modalities available – digital, USS, EMG, balloon manometry. Rectal balloon
- Neuromuscular electrical Stimulation (NMES) – funded by League of Friends. Deposit for equipment required from patients.
- Acupuncture / electropuncture / PTNS – currently only offered for urinary incontinence
- Modified Pilates and functional circuit classes
- Constipation treatment – lifestyle advice, regular exercise regimes, dietary advice, abdominal massage, perineal support, postural and dynamic changes to facilitate defaecation, laxatives, biofeedback. Methods found to be unlikely to be helpful in presence of prolapse.
- ODS – diet, biofeedback, rectal balloon sensitivity, postural changes
- Faecal incontinence treatments
- Flatulence treatment – dietary change, electrostimulation
- Prolapse management
- 3-4<sup>th</sup> degree tears

- Objective measures available for assessment but subjective assessment of patient appears more relevant
  - The latest development is joint clinics with Colorectal Consultants
    - Fortnightly joint clinics with physio and Consultant Surgeon
    - Patients seen – FI, constipation, ODS, rectal prolapse (pre/post op), 3<sup>rd</sup>-4<sup>th</sup> degree tears
    - Benefits: earlier PT intervention and f/up, improve RTT performance, MDT approach, enhance patient experience
- The presentation was extremely well received.

### 3. Unit Updates

Southend (BP) – Southend has won a centre of excellence award for PTNS. It is thus only to win awards in urinary incontinence and faecal incontinence

- There is a perineal trauma day being run at Southend on 4<sup>th</sup> June (being run by the Gynaecologists)

Ipswich (A Malik) – Looking into devices/machines for Endoanal USS. SV presented options available including BK.

West Suffolk (AM) – has also been looking into setting up Endoanal USS

- Meeting radiology department next week to discuss proctograms
- Certain delays in development due to knock on effects of junior doctors' strikes

### 4. Research update.

- Mr Malik presented a literature update

- 1) The Diagnostic Value of a Digital Rectal Examination Compared With High-Resolution Anorectal Manometry in Patients With Chronic Constipation and Fecal Incontinence – Soh et al Am J Gastroenterol 2015; 110:1197–1204; doi:10.1038/ajg.2015.153; published online 2 June 2015
  - a. DRE was 93% sensitive and 58% specific for assessment of anismus in constipation
  - b. DRE was poor for evaluating resting tone in FI (kappa 0.07)

SS discussed the importance of a physiotherapist's DRE – ease / timing / environment etc

- 2) Libertas: rationale and study design of a multicentre, Phase II, double-blind, randomised, placebo-controlled investigation to evaluate the efficacy, safety and tolerability of locally applied NRL001 in patients with faecal incontinence. Siproudhis et al. Colorectal Dis. 2014 Mar;16 Suppl 1:59-66. doi: 10.1111/codi.12546.

- a. leading from the previous work, this an RCT comparing responses in 5 groups with different doses of NRL001.

**Update: “unexplained improved sustained placebo response”!  
(Abstract attached)**

Int J Colorectal Dis. 2016 Apr 13. [Epub ahead of print]

Libertas: a phase II placebo-controlled study of NRL001 in patients with faecal incontinence showed an unexpected and sustained placebo response.

Siproudhis L1, Graf W2, Emmanuel A3, Walker D4, Shing RN5, Pediconi C5, Pilot J5, Wexner S6, Scholefield J7.

**Abstract**

**PURPOSE:**

Faecal incontinence (FI) is distressing, significantly reduces quality of life (QoL) and has few pharmacological treatments. The  $\alpha$ 1-adrenoceptor agonist NRL001 (1R,2S-methoxamine hydrochloride) improves anal sphincter tone. NRL001 efficacy was evaluated by changes in Wexner scores at week 4 vs. baseline in NRL001-treated patients compared with placebo. Impact of NRL001 on QoL and safety were also assessed.

**METHODS:**

Four hundred sixty-six patients received NRL001 (5, 7.5 or 10 mg) or placebo as suppository, once daily over 8 weeks. Wexner score, Vaizey score and QoL were analysed at baseline, week 4 and week 8. FI episodes and adverse events were recorded in diaries.

**RESULTS:**

At week 4, mean reductions in Wexner scores were -3.0, -2.6, -2.6 and -2.4 for NRL001 5, 7.5, 10 mg and placebo, respectively. All reduced further by week 8. As placebo responses also improved, there was no significant treatment effect at week 4 ( $p = 0.6867$ ) or week 8 ( $p = 0.5005$ ). FI episode frequency improved for all patients, but not significantly compared with placebo (week 4:  $p = 0.2619$ , week 8:  $p = 0.5278$ ). All patients' QoL improved, but not significantly for all parameters ( $p > 0.05$ ) except depression/self-perception at week 4 ( $p = 0.0102$ ) and week 8 ( $p = 0.0069$ ), compared with placebo. Most adverse events were mild and judged probably or possibly related to NRL001.

**CONCLUSIONS:**

All groups demonstrated improvement in efficacy and QoL compared with baseline. NRL001 was well-tolerated without serious safety concerns. Despite the improvement in all groups, there was no statistically significant treatment effect, underlining the importance of relating results to a placebo arm.

- 3) Review of medical treatments / antidiarrhoeals in use of FI  
Rao SS, J Clin Gastroenterol. 2014 Oct;48(9):752-64.

**Little evidence to guide clinicians in selection of drug  
treatment for FI. Abstract attached.**

Current and emerging treatment options for fecal incontinence.

Fecal incontinence (FI) is a multifactorial disorder that imposes considerable social and economic burdens. The aim of this article is to provide an overview of current and emerging treatment options for FI. A MEDLINE search was conducted for English-language articles related to FI prevalence, etiology, diagnosis, and treatment published from January 1, 1990 through June 1, 2013. The search was extended to unpublished trials on ClinicalTrials.gov and relevant publications cited in included articles. Conservative approaches, including

dietary modifications, medications, muscle-strengthening exercises, and biofeedback, have been shown to provide short-term benefits. Transcutaneous electrical stimulation was considered ineffective in a randomized clinical trial. Unlike initial studies, sacral nerve stimulation has shown reasonable short-term effectiveness and some complications. Dynamic graciloplasty and artificial sphincter and bowel devices lack randomized controlled trials and have shown inconsistent results and high rates of explantation. Of injectable bulking agents, dextranomer microspheres in non-animal stabilized hyaluronic acid (NASHA Dx) has shown significant improvement in incontinence scores and frequency of incontinence episodes, with generally mild adverse effects. For the treatment of FI, conservative measures and biofeedback therapy are modestly effective. When conservative therapies are ineffective, invasive procedures, including sacral nerve stimulation, may be considered, but they are associated with complications and lack randomized, controlled trials. Bulking agents may be an appropriate alternative therapy to consider before more aggressive therapies in patients who fail conservative therapies.

- 4) SAFARI Trial:5) SaFaRI: sacral nerve stimulation versus the FENIX™ magnetic sphincter augmentation for adult faecal incontinence: a randomised investigation. Williams et al. Int J Colorectal Dis. 2016 Jan 12. [Epub ahead of print].
  - a) SaFaRI will evaluate a new technology for faecal incontinence, the FENIX™ MSA.

#### **Results expected – 2022**

- 5) A history of litigation issues with regards to use of mesh in pelvic organ prolapse was presented
  - issues raised particularly in TV repair and in SUI
  - Surgical mesh panel meeting in September 2011 decreed that the safety of mesh for pelvic organ prolapse has not been established
  - York report claimed a mesh erosion occurrence of 6% (though over what time period?), and reported sexual dysfunction at 15%.
  - This led to a discussion about the possibility of creating a joint Lap VMR patient information sheet (PIS) for the group. Currently units of adapted existing PIS forms from other centres.
  - BP mentioned using oestrogen cream in potentially atrophic vaginas pre and post-op
  - a discussion occurred over choice of sutures for mesh fixation – most members had moved to using PDS (ie a monofilament), although one person preferred to use ethibond

#### **5. New case presentations**

- SV presented a 28 year old lady with with rectal prolapse. She had already 3 children, and the first birth was complicated by a 4<sup>th</sup> degree tear at the age of 14. She subsequently underwent a laparoscopic

appendicectomy and unfortunately had a small bowel perforation for which she had a laparotomy and small bowel resection. She then developed a rectal prolapse 3 years ago for which she underwent a Delorme's procedure. Unfortunately this has now recurred and has been referred to SV for further management. Of note, she also has a uterine prolapse and suffers with menorrhagia. Her family is complete.

- Options suggested
  - 1) proceed with Altemeiers while awaiting hysterectomy – thus proceeding with treatment while awaiting 8 month wait for gynae surgery. Accept may recur.
  - 2) proceed with hysterectomy, allow things to heal, and then consider Laparoscopy +/- lap/open adhesiolysis +/- lap VMR.
- BP presented a 40 year old female patient she has been referred with a recurrence after LVMR. The recurrence is posterior lateral
  - Options: laparoscopy and evaluate mechanism of prolapse
  - STARR procedure
  - Modified Orr-Loygue procedure

## **6. AOB - Paula Hughes**

PH informed us that she had been made redundant by EES. The group as a whole were shocked and saddened to hear this. We are grateful for everything she has done to bring the group together and her contributions to the Pelvic Floor Society as a whole. We are delighted that she will be available in a consulting capacity in the future and will no doubt collaborate further.

## **7. Items for next meeting: proposed for Wednesday 14<sup>th</sup> September 2016, Pontlands Hotel**

- Lap VMR experience of group
- Pilates experience for pelvic floor dysfunction – Sam Head
- Rectal irrigation data – BP, Southend

AM 20th April 2016