Welcome

Welcome to the December 2016 edition of NewWave.

If you have any relevant articles or papers that you would like to be included in future editions, please email them to steve.perring@poole.nhs.uk

Contents:
Page 2: Members news—The Bursary Scheme
Page 3: Obituary, Roy Anggiansah
Page 4: Meeting list
Page 5: The importance of pre-soaking pH catheters
Page 7: Advice about reporting failing equipment
Page 8: The AGIP Masterclass in Upper GI Physiology
Page 11: A review of the ICS meeting in Tokyo by Samantha Morris and an abstract of her presentation at that meeting
Page 14: A report from the Chief Executive of the RCCP
Page 16: A report on rectal balloon physiology and outcome of SNS surgery by Ismail Miah

December 2016
The AGIP bursary scheme is happening again! We have extended the scheme to fund attendance at the BSG Annual Meeting to be held in Manchester in June 2017. We are particularly keen to encourage people to submit abstracts of original research for the meeting and applicants who have submitted abstracts will be given preference in terms of a successful application. AGIP have a significant presence at this meeting and would welcome more contribution from AGIP members.

The bursary scheme will be for up to £500 per applicant and include allocation of a session for successful applicant to review and be subsequently published in NewWave. Deadline for applications will be January 31st 2017. If you need help in writing an abstract a mentoring scheme is available to AGIP members. For more details of this and the bursary scheme in general please contact Dr Anthony Hobson (anthonyhobson@hotmail.com).
Obituary

Roy Anggiansah: 14th January 1949 – 21st October 2016

Roy was born in Indonesia and came to the UK in 1972. He graduated in Electrical Engineering from St Mary’s University and pursued a successful career in Engineering. He also obtained an MSc at the Bio-Engineering Unit at the University of Strathclyde and later joined his wife Angela at the Oesophageal Unit at Guys and St Thomas’s working initially under William Owen and latterly with Terry Wong. He was a member of AGIP/BSG and completed our module in Upper GI Physiology. He actively participated in both the clinical service and the research undertaken at GSTT until Parkinson disease made work impossible.

Roy had a great passion for life, he was gregarious, always telling jokes and above all fun. He never took life too seriously and had a great love of good food and good company. He died peacefully after a long illness on 21st October 2016. We extend our sincere sympathy to his wife Angela and his son Clive and his family.
Forthcoming Events 2016/2017:

25th-27th Jan 2017  
The Pelvic Floor Society Annual Meeting  
The Hilton Hotel, Cardiff  
Essential meeting for all professionals involved in pelvic floor Diagnosis and treatment  
http://thepelvicfloorsociety.co.uk/pages.php?s=Cardiff-Meeting-Jan-2017&section=43

25th-27th Jan 2017  
The British Society of Paediatric Gastroenterology, Hepatology Nutrition Annual Meeting  
Glasgow  
https://bspghan.org.uk

1st March 2017  
AGIP Masterclass in Upper GI Physiology  
Details page 8

6th-9th May 2017  
Digestive Disease Week  
Chicago  

19th-22nd June 2017  
BSG Annual Meeting  
Manchester  

CATHETER FREE, WIRELESS DIAGNOSIS OF GASTRO OESOPHAGEAL REFLUX DISEASE (GORD)

The pH value monitored continuously for 4 full days (96 hours) of acid detection.
Data wirelessly transmitted to the external data recorder.
The pH capsule will naturally drop off from the mucosa and exit the body.

Introducing a competitive pH capsule wireless monitoring system

The Synmed delivered pH capsule wireless monitoring system is used to record the pH value inside the oesophagus to aid in the diagnosis of Gastro Oesophageal Reflux Disease (GORD).

The pH capsule is fixed to the oesophageal mucosa using a simplified delivery device.

Unlike conventional pH catheters patients are less aware of the procedure and more likely to maintain their regular lifestyle, activities and diet providing the clinician with more realistic profile of the frequency and severity of the acid reflux.

ADVANTAGES OF THE pH CAPSULE WIRELESS MONITORING SYSTEM INCLUDE:

- Simplified capsule releasing process, using 3 switches
- Improved data integrity and reduced artifact
- Dry reference electrode resulting in longer shelf life.

FOR FURTHER INFORMATION AND EVALUATION CONTACT: Email sales@synmed.co.uk  Telephone 01992 782570
Synectics Medical Ltd (TA Synmed) Synmed House, 7 The Pavilion Business Centre, 6 Kinetic Crescent, Innova Park, Enfield EN3 7FJ  Website www.synmed.co.uk
The Importance of Pre-Soaking pH and MII Impedance Catheters to Ensure Accurate pH Measurement

Steve Perring, Poole Hospital NHS Foundation Trust

Most pH catheters used for in-vitro measurement of intra-luminal pH in humans use antimony-tipped catheters that have an internal reference electrode. It takes some time for this internal reference electrode to be sufficiently wetted to act effectively and thus for a stable emf to be generated for a stable pH solution. Accordingly most manufacturers state a minimum time that the catheters need to be soaked for before they can be accurately calibrated.

Our catheter supplier recently changed their manufacturer and initially we had trouble calibrating the catheters with our Sandhill Zephr recording devices. These issues were largely resolved when we increased our pre-soak time from the recommended 10 minutes to at least 30 minutes. However an audit of the analogue-to-digital (ADC) output of the Sandhill recorders during calibration in pH4 and pH7 buffer solutions revealed a surprisingly large variation in emf even for catheters from the same batch.

<table>
<thead>
<tr>
<th>Catheter Type</th>
<th>Batch Number</th>
<th>Number of Catheters Tested</th>
<th>ADC output in pH4 buffer solution Mean (SD)</th>
<th>ADC output in pH7 buffer solution Mean (SD)</th>
</tr>
</thead>
<tbody>
<tr>
<td>MII Impedance</td>
<td>31A4315</td>
<td>33</td>
<td>965 (68)</td>
<td>1691 (35)</td>
</tr>
<tr>
<td>Single channel</td>
<td>00A5315</td>
<td>28</td>
<td>873 (23)</td>
<td>1657 (30)</td>
</tr>
</tbody>
</table>

To explore further how the catheters respond to soaking, we repeatedly went through the calibration process for a number of catheters over a period of at least 1 hour, each time recording the ADC outputs corresponding to the pH4 and pH7 buffer solutions. Below are graphs indicating how the emf output from the ADC in the Sandhill Zephr system varied with soaking time for four catheters of the same type (BD-31 MII impedance/ pH) and batch number (31A5115). One catheter examined (catheter 3) failed to calibrate over a period of 30 minutes soaking as the ADC output in pH4 buffer was too high for the Sandhill Zephr firmware to accept as valid.
The following may be noted from this study:

1. The minimum soaking period of 10 minutes as stated on the packaging of this type of catheter is totally inadequate to establish a stable emf output from the catheters assessed.
2. The pattern of change of the emf output with soaking time is not consistent between catheters even from the same batch
3. It appears that the catheter emf output is not stable until at least 50 minutes of soaking
4. For catheter 2 the error in calibration if the calibration were to have been performed after only 10 minutes of soaking would amount to approximately a 0.8pH unit offset in the measured pH value as the catheter continued to settle with further soaking in vitro.

Conclusions:

It is worth checking pH sensors to establish how quickly their internal reference electrodes become effectively wetted and plan investigations to include sufficient time to allow adequate soaking. Do not necessarily rely on the manufacturer’s claims for the minimum soak time.
Dear Colleagues,

Just a short note to bring to your attention that if any of your medical devices (i.e. catheters pH +/- Impedance catheters etc.) are not up to the standard you expect then you must report this to the device company that supplied you with the faulty equipment.

It is our responsibility as practitioners to check to ensure that our equipment is working to its specification and to act promptly if it fails to do so.

If the matter is persistent (multiple failures of a similar device) or you feel the issue has not been resolved to your satisfaction then you must seek further guidance through the Medicines and Healthcare products Regulatory Agency (MHRA) which is a government body set up in 2003 to bring together the functions of the Medicines Control Agency (MCA) and the Medical Devices Agency (MDA). For further information please visit www.mhra.gov.uk

To download important information on ‘Medicines & Medical Devices Regulation: What you need to know’ - CLICK HERE

Kind regards,

The AGIP Council
AGIP Upper GI
Physiology Masterclass
in Good Practice

Date
Wednesday 1st March 2017

Location
Post Graduate Education Centre, Queen Elizabeth Hospital, Birmingham, B15 2GW

Goal
To enhance techniques and knowledge of ways in which High Resolution Oesophageal Manometry (HRM) and 24hour pH/Impedance monitoring and analysis can improve the clinical assessment of patients presenting with oesophageal pathophysiology

Target audience
Clinical GI Physiologists, Clinical Scientists, Surgeons and Gastroenterologists with an interest in oesophageal pathophysiology and Nurse Specialists

Course highlights
- Advances in GI Physiology Measurement
- Update on the new BSG Oesophageal Guidelines
- Chicago Classification V3 and beyond...Provocation Techniques to Answer Clinical Questions
- Interactive demonstrations of the HRM and 24hour pH/Impedance software (case studies may be brought for analysis) via a breakout session
- Tips and tricks to analysis
- New training pathways within GI Physiology, membership of AGIP, Accreditation and Registration updates
- Problem based learning via clinical case studies
- Treatment options will be discussed

Cost
Free for AGIP members
£ 100.00 for non-AGIP members

Registration
Please see attached form
AGIP Upper GI
Physiology Masterclass in Good Practice

Wednesday 1st March 2017

Post Graduate Education Centre, Queen Elizabeth Hospital, Birmingham, B15 2GW

10.00 – 10.30 Registration and coffee

10.30 – 10.40 Welcome (AGIP Chair) Warren Jackson

10.40 – 11.00 Advances in GI Physiology Measurement Anthony Hobson

11.00 – 11.20 Oesophageal Guidelines (Oesophageal Section Chair) Stephen Attwood

11.20 – 11.40 High Resolution Manometry – Chicago Classification V3 Rami Swels

11.40 – 12.00 Coffee break

12.00 – 12.20 Beyond Chicago – Provocation Techniques to Answer Clinical Questions Rami Swels

12.20 – 12.40 pH/Impedance Monitoring Caroline Race

12.40 – 13.30 Lunch

13.30 – 14.20 HRM and Impedance + Impedance /pH Analysis Step by Step Guide Breakout Session

[...delegates rotate around the equipment they would like to observe... will include pitfalls to analysis]

HRM and Impedance MMS: Warren Jackson / Diagmed: Sarah Kelly / Sandhill: Andres Vales

Impedance /pH MMS: John Casey / Diagmed: Caroline Race / Sandhill: Steve Perrill

14.20 – 14.30 Accredited Scientific Practice Programme (AGIP Education Secretary) Sarah Kelly

14.30 – 14.40 RCCP / AHCS Update (RCCP Chief Executive) Paul Sharpe

14.40 – 14.50 AGIP Membership & Accreditation (AGIP Accreditation Officer) Tanya Miller

14.50 – 15.10 Coffee break

15.10 – 16.10 Problem based learning – Delegates split into groups and are presented with a clinical case. They are given the opportunity to design the acquisition protocol and possible testing regimen for each patient and then analyse the raw data files, come up with a diagnosis and suggestions on how testing could have differed and what complementary investigations may have (or not) helped. Each group briefly discuss (within their group) with feedback at end from the faculty

15.10 – 16.40 Treatment Options Phil Woodland

16.40 – 16.50 Completion of Feedback Forms & Receive Attendance Certificates
Registration Form

AGIP Upper GI Physiology Masterclass in Good Practice
Wednesday 1st March 2017
Post Graduate Education Centre, Queen Elizabeth Hospital, Birmingham,
B15 2GW

Name: ..............................................................................................................Title: ................................

Institution: .....................................................................................................

Address: .....................................................................................................

Postal code: ......................

Current position: .......................................................................................

E-mail: ........................................................................................................

Telephone: ................................................................................................

Special dietary requirements: ......................................................................

Payment:

The registration fee is free for AGIP members and £100 for non AGIP members, includes lunch and coffee breaks.

Please post completed application form (with cheque made payable to BSG) to:

Warren Jackson, GI Physiology, Castle Hill Hospital, Castle Road, Cottingham, East Yorkshire, HU16 5JQ

Your place will not be reserved until your cheque and registration form is received. Please note there will be no refunds for non-attenders. If you are a member of AGIP your cheque will be returned to you on the day.

I am / I am not* (*delete as appropriate) a member of AGIP

I agree to the above

Date: ................................................ Signature: ..............................................
Last September I was lucky enough to attend the 46th International Continence Society (ICS) 2016 conference in Tokyo and presented my research. I am very grateful to the ICS for awarding me with the ICS Travel Award, which was a huge help in enabling me to attend.

The ICS itself is, as its name suggests, an international society with members spreading across the world. It is involved with all things related to continence – both bladder and bowel. It originally set out to establish standardisation of terminology across the globe, and has gone on to publish many papers on this within different subspecialty groups. Although originally thought to be more urology focused, the ICS is branching out more and more into the lower GI and colorectal fields. The 2016 conference lasted for 4 days and I would say without a doubt it was the best conference I’ve been to so far. Its opening ceremony was a showcase of traditional Japanese dancing, performed by a local dance company, who invited us all to join in. This was an excellent opportunity to first embrace our host nation and to meet other delegates of the conference. The days that followed included a variety of workshops, podium and oral e-poster presentations. The workshops were varied, spanning across the three disciplines involved in pelvic floor – colorectal, gynaecology and urology. My unit ran a workshop on pelvic floor defecatory dysfunction, looking at pathology, diagnostic tests and both conservative management, including biofeedback and rectal irrigation, and surgical treatment. I also attended a urodynamics workshop run by the Bristol team, which brilliantly covered all aspects of urodynamics from performing to reporting, increasing my confidence. It was also an excellent opportunity to meet others across the world who also perform urodynamics testing, and learn from them about their similar and different experiences in their varied cultures and healthcare set ups.

During the conference I presented my research as an open discussion e-poster. This was an oral presentation performed whilst using what can only be described as a giant interactive iPad, that could be used to zoom in and move on the poster to illustrate key points, followed by discussion from the watching crowd. I enjoyed this style of presenting, as I felt I could really interact with those watching to discuss my findings.

The ICS also runs a WIKI page (which can be found on the ICS website), where different symptoms and pathologies are debated and definitions defined with space for discussion. I recently became an editor on this, and so the conference was an excellent opportunity for me to meet fellow members of the WIKI team who I had only previously spoken with via email.

ICS 2017 is in Florence, Italy from 12th - 15th September and I highly recommend it. Nowhere else can you meet with doctors, nurses, physiotherapists and physiologists from across the world, all with an interest in incontinence. The ICS has not been in Europe since the 2013 meeting in Barcelona, so this is the year to try to attend! Don’t let finances put you off – if it is your first time going, you can apply for the ICS Travel Award. This is a prize up to £1000, covering your travel, accommodation, conference fees and a workshop on the conference. I didn’t think I would be in much of a chance of receiving the award, but I did, so I definitely recommend giving it a go. Deadline for workshops is 4th January 2017 and for abstracts is 1st April 2017. Plus, a trip to Italy is always fun.
Hypothesis / aims of study

Endovaginal ultrasound (EVUS) scanning is a component of total pelvic floor ultrasound assessment, routinely used to assess women with pelvic floor dysfunction. Women with levator plate injury on endovaginal ultrasound (EVUS) have a 7-fold increase in chance of developing ‘obstructive defecation’. The role of EVUS is to assess alignment of the pelvic floor structures and diagnose levator plate injury by assessing insertion of the levator muscles into the pubic ramus, which can be graded according to degree of injury. The aim was to determine if the position of the probe affects the accurate diagnosis of pelvic floor injury and a shift in pelvic floor structures.

Study design, materials and methods

50 women - 40 parous, mean aged 46 (19 – 80) - with defaecatory dysfunction underwent vaginal examination, EVUS (central, left and right position) and wide-view endoanal ultrasound (EAUS) for control. Both the EVUS and the wide-view EAUS were performed using a BK 8838 axial type endoscopic probe with a 12 MHz transducer (B & K Medical, Sandhoften, Denmark). The EVUS probe was positioned in the vagina using the bladder neck as the cranial landmark. 3D scans were procured in the centre, left and right side of the vagina to assess the effect of positioning on the analysed outcome. Each procured image was analysed to assess alignment, the presence of levator plate injury on initial visual assessment (our current routine practice) and the degree of injury by staging levator ani muscle defects [1]. This grading system looks at the puboperinealis/puboanalis (PA), puborectalis (PR) and iliococcygeus/ pubococcygeus (PV), scoring each in terms of degree of muscle loss, with the total combined score classifying the levator muscle as normal (score of 0), mild (score of 1-6), moderate (score of 7-12) or severe (score of 13-18).

Results

On visual assessment without staging, on EAUS, 47 showed alignment with 5 levator plate injuries. On EVUS, when great care was taken to accurately position the probe in the centre, 11 had a levator plate injury and 3 scans showed malalignment. These results were similar to the findings from the vaginal examination. However, when the probe was positioned to the left or right of the vagina, to represent inaccurate positioning, there were a greater number of cases of malalignment and levator plate injury.

<table>
<thead>
<tr>
<th></th>
<th>EAUS</th>
<th>Centre EVUS</th>
<th>Right EVUS</th>
<th>Left EVUS</th>
<th>PV Assessment</th>
</tr>
</thead>
<tbody>
<tr>
<td>Malaligned</td>
<td>3 (6%)</td>
<td>3 (6%)</td>
<td>6 (12%)</td>
<td>9 (18%)</td>
<td>/</td>
</tr>
<tr>
<td>Right Injury</td>
<td>5 (10%)</td>
<td>9 (18%)</td>
<td>2 (4%)</td>
<td>28 (56%)</td>
<td>7 (14%)</td>
</tr>
<tr>
<td>Left Injury</td>
<td>0 (0%)</td>
<td>2 (4%)</td>
<td>29 (58%)</td>
<td>2 (4%)</td>
<td>2 (4%)</td>
</tr>
</tbody>
</table>

N (%) = number of patients (percentage of total patients)

When staging the degree of levator plate injury on each scan, it was again shown that when the EVUS probe was not centrally placed, the grading scores tended to be higher than when it was carefully positioned in the centre resulting in a higher classification of injury. However, the EAUS also showed a higher proportion of injuries when using this classification.
Also if you have some interesting research or an interesting case that you would like to share with the AGIP community in a future edition of NewWave, please contact me at steve.perring@poole.nhs.uk

Budding Reviewers

If you attend a meeting and wish to review a presentation at that meeting in a future edition of NewWave, please contact the NewWave editor (steve.perring@poole.nhs.uk)

Help-out the rest of us who did not manage to get to the meeting

<table>
<thead>
<tr>
<th></th>
<th>EAUS</th>
<th>Centre EVUS</th>
<th>Right EVUS</th>
<th>Left EVUS</th>
</tr>
</thead>
<tbody>
<tr>
<td>Mean</td>
<td>8 (Moderate)</td>
<td>4.5 (Mild)</td>
<td>7 (Moderate)</td>
<td>7.1 (Moderate)</td>
</tr>
<tr>
<td>Median</td>
<td>9 (Moderate)</td>
<td>4 (Mild)</td>
<td>6 (Mild)</td>
<td>8 (Moderate)</td>
</tr>
<tr>
<td>Mode</td>
<td>10 (Moderate)</td>
<td>2 (Mild)</td>
<td>6 (Mild)</td>
<td>9 (Moderate)</td>
</tr>
<tr>
<td>Min</td>
<td>0 (Normal)</td>
<td>0 (Normal)</td>
<td>2 (Mild)</td>
<td>1 (Mild)</td>
</tr>
<tr>
<td>Max</td>
<td>12 (Moderate)</td>
<td>12 (Moderate)</td>
<td>14 (Severe)</td>
<td>12 (Moderate)</td>
</tr>
</tbody>
</table>

$X \text{ (Classification)} = \text{Grading (Classification)}$

**Interpretation of results**

Levator plate injury and malalignment is overcalled if the probe is incorrectly positioned within the vagina. This study shows that reported cases of malalignment and levator plate injury may not be accurate if great care is not taken to accurately perform the EVUS. As the EVUS is technically difficult to perform, initial assessment should be performed with the wide-view EAUS to determine if there is malalignment or a levator plate injury. However, staging of the injury is not accurate with the EAUS. This is predominately because the insertion of the PA muscle was difficult to distinguish, causing the injury to be consistently scored higher. Thus if an injury or malalignment is found on the EAUS, a centre-positioned EVUS should then be performed to stage. There is also a possibility that as the PV examination tallied with the centre EVUS in determining injury, if staging is not required for clinical treatment, just an PV examination will suffice, with no ultrasound needed.

**Concluding message**

Correct positioning of the EVUS is essential for accurate assessment of levator plate injury and pelvic floor alignment and avoid overcalling injury. For accurate assessment, a wide-view EAUS scan should be performed, followed by a centre-positioned EVUS only if injury is found and staging required for clinical decisions.
REGULATION RETHOUGHT

The Professional Standards Agency (PSA) have been having a think about how the Healthcare sector might be better regulated and that could influence how Clinical Physiologists are regulated.

‘Regulation rethought’ is a paper published by the (PSA) in October 2016. Paul Sharpe, Chief Executive of the Registration Council for Clinical Physiologists (RCCP) highlights some of the points made by the PSA and looks at how the regulatory regime for Clinical Physiologists might be better delivered.

The PSA run an oversight regime of the statutory regulators in healthcare and also provide a voluntary accreditation of the voluntary regulators. The paper ‘Regulation rethought’ can be viewed here:

http://www.professionalstandards.org.uk/publications/detail/regulation-rethought

It is a follow up to a paper called ‘Rethinking Regulation’ published by the PSA in August 2015 which can be reviewed here:

http://www.professionalstandards.org.uk/publications/detail/rethinking-regulation

What are the issues that the PSA have identified?

- Employers have to engage with multiple regulators in order to check their worker’s registration, report concerns, support revalidation and continued professional development.
- People in multi-disciplinary teams work to different standards set by different regulators for the same or similar pieces of work.
- Educators are affected by multiple regulators with different standards and quality assurance mechanisms.
- Regulators should shift their focus and expenditure to the prevention of harm and the maintenance of standards – so should look to save costs and work done elsewhere.
- Working in silos with separate objectives dilutes regulatory impact.
- There would be merit in merging regulators to simplify access, improve efficiency and reduce costs.
- Regulation should not be applied by job title but on the basis of risk to service users.
- Risk is a function of the type of work done, the level of supervision under which the work is carried out and the vulnerability of service users and their ability to understand and measure the type of work delivered to them. PSA have proposed a risk measuring tool which can be reviewed here:


- The risk from some activities which are currently statutorily regulated could probably be adequately mitigated by forms of non statutory regulation and the risk from some activities which are not currently statutorily regulated is such that they probably should be statutorily regulated.
- Improvements can be achieved through collaboration, innovation, imagination and determination.

What does this mean for Clinical Physiologists?

It is true that many of the observations made by the PSA in their documents apply to the statutory regulators, but they can equally be applied to the regulatory regimes which exist in the voluntary regulatory framework that Clinical Physiologists operate under. Two regulatory regimes currently exist, one operated by the Academy of Healthcare Science (AHCS) – who have a register accredited by PSA and another, a longer established and larger register operated by the Registration Council for Clinical Physiologists (RCCP).

In my short time sitting on the Council of RCCP, and even shorter time as its Chief Executive, I’ve witnessed:

- Confusion amongst patients about where to go with concerns that they have.
- Confusion amongst employers about which organisation(s) to suggest for registration requirements in job adverts – if any at all.
- Confusion amongst educators about which organisation to apply for course accreditation, if any at all.
- Confusion amongst registrants about which organisation to register with – if any at all.
- Regulatory shortcomings arising from problem practitioners jumping from one register to another and into the gap which exists between both.
- A likely cost burden on practitioners as two organisations each duplicate what the other is doing

Furthermore, both organisations do other things apart from offering voluntary regulation – RCCP campaigns for statutory regulation in the Clinical Physiology sector and accredits education courses, while AHCS provides equivalence, quality assurance and commissioned consultancy type work.

What can be done about a solution?
Can we use “collaboration, innovation, imagination and determination” to better deliver regulatory outcomes for Clinical Physiologists and the people who use the services that they provide?

This is a question that has been asked many times over the years and most recently in May 2015 when representatives from AHCS and RCCP met to discuss the imperfect solution that AHCS and RCCP currently are to the regulatory regime required in Clinical Physiology and in Healthcare Science.

The process has been like a journey where we have some idea of the direction of where the destination is, but we don’t know exactly where it is and we don’t have a map to show us how to get there. We’ve inevitably made some wrong turns and gone down a few cul-de-sacs. And we’re still not at the destination – but we are a lot closer to it.

A meeting in November 2016 between representatives of the RCCP, its professional bodies (including the ARTP Chairman) and AHCS Board members determined that:

- Doing nothing and maintaining the status quo was not an option
- An option of combining all of the services that both organisations currently do into one organisation was equally unappealing. Both organisations have history and standing and there is value in their names and what they do and it would be a shame to lose that by losing one or both of the names or brands.
- There was huge support for identifying areas that both AHCS and RCCP currently do the same or similar and doing that together and while both organisations continue to do what they do differently.

What that solution will look like in detail is the challenge ahead and a working group made up of representatives from RCCP (including professional bodies) and AHCS starts work in January 2017 with a goal of finalising the solution in the first quarter of 2017 for launch and delivery later in the year.

What does this mean for RCCP?

It’s too early to say what RCCP will look like in the future if it ceases to have a regulation/register function to operate. For years RCCP has campaigned for statutory regulation for Clinical Physiologists and the reasons for that have not gone away - and won’t go away once a new regulatory solution has been developed. The new regulatory solution should be better placed to deliver greater safety for service users, not least because it will be less easy for practitioners to hide. But any solution will still be voluntary and problem practitioners will still have the option to not be part of any of it and that is a risk to service users. So the campaign for statutory regulation must continue, though it will probably change to be more responsive to the rethinking of regulation outlined by PSA and the risk measurement model that PSA have published.

Paul Sharpe, Chief Executive
Registration Council for Clinical Physiologists, City Wharf, Davidson Road, Lichfield, Staffs WS14 9DZ
chiefexec@rccp.org.uk
Rectal Balloon Studies Predict the Outcome of Sacral Nerve Stimulation in Patients with Constipation: A Pilot Study

By Ismail Miah

Introduction
Rectal balloon distension (RBD) study has been in routine clinical practice for more than two decades without receiving much clinical appraisal for guiding management of patients with pelvic floor disorders. The aim of this pilot study is to retrospectively investigate the preoperative RBD sensory threshold markers in patients who underwent a trial of sacral nerve stimulation (SNS) for their constipation symptoms.

Method
Patients recruited for this study were complaining of constipation (without faecal incontinence) and underwent complementary anorectal physiology testing which was followed up with comprehensive conservative management prior to undergoing SNS trial.

i) The inclusion criteria from the anal manometry & RBD testing was restricted to patients demonstrating normal internal & external anal sphincter function, presence of rectoanal inhibitory reflex mechanism and absence of paradoxical sphincter contraction during strain manoeuvre.

ii) Those patients from i remained within the inclusion when they did not respond to the conservative management which included attending ≥2 biofeedback therapy sessions with teaching techniques for toilet positioning and diaphragmatic breathing to aid bowel evacuation, dietary and lifestyle modifications for stool consistency, judicious use of laxatives and suppositories and receiving basic psychology education on effects of emotion and stress on the bowel function.

iii) The final inclusion criteria was of patients who fulfilled i & ii and successfully underwent temporary SNS treatment for 2-3 weeks without postsurgical complications and completed pre- and post SNS therapy bowel symptom questionnaires recommended by manufacturer (Medtronic).

The total number patients recruited for the study was 41 (male:female =2:39, age range=24–50years) and successful SNS outcome was considered if patient demonstrated improvement in their constipation symptoms by >50% otherwise considered as failed SNS outcome. The statistical analysis of the RBD sensory threshold markers (threshold volume [TV], urge volume [UV] & maximum tolerated volume [MTV]) between successful & failed SNS outcomes was conducted using two-tailed t-test. Fischer’s exact test was also employed for the overall sample to compare patients with normal and hyposensitive rectum (deemed by RDB studies) against the SNS outcomes. The cut-off for normal and abnormal volumes to induce RDB sensory thresholds were benchmarked against St Mark’s normal values and a p-value of <0.05 in tests was considered statistically significant.

Results
68.3% (28) of patients responded to SNS treatment for constipation. There was no crossover between the normal and abnormal RDB sensory threshold markers, such that, patients displayed either having normal rectal sensitivity in all 3 sensory threshold markers or rectal hyposensitivity in all 3 sensory threshold markers. There was statistical differences in all the RBD sensory threshold markers between the patients with successful and failed SNS outcomes for managing constipation (see table 1). Overall, 82.8% (24/29) of the patients with normal rectal sensitivity responded to SNS treatment whereas 61.5% (8/13) of the patients with rectal hyposensitivity did not respond to SNS treatment (p=0.0036).
Discussion
Constipation in patients is not routinely managed with SNS treatment but the current study revealed that greater than two-thirds of patients with intractable constipation to conservative management respond to SNS and a further >80% of these patients being considered for SNS suitability may be dictated by a preoperative RBD study thereby voiding patients, who display rectal hyposensitivity on RBD, undergoing unnecessary temporary SNS trial for 2-3 weeks which is an invasive surgical technique requiring theatre environment & time with anaesthetist availability and the treatment itself has been associated with postsurgical complications (sacral pain, site infection and SNS lead migration requiring secondary corrective surgery etc.).

The findings suggest that SNS therapy for constipation is effective when patients demonstrate normal RBD sensory thresholds markers. The pathology of the RBD threshold volume markers may advocate patients i) perceiving good sensory to minimal rectal distension from normal TV volumes, ii) having normal urges for defaecation from the normal UV volumes and iii) patients having normal rectal capacities from the MTV volumes. Furthermore, if these rectal sensory markers are normal for successful SNS therapy we can then assume these patients have intact neural pathway and normal biomechanics of the rectum which may explain the success of SNS treatment. These findings may contribute further our understanding or pave a new dimension to explain how SNS function in managing patients with constipation. Further complementary studies, to assess the neuropathway integrity, would be to compare brain EEG/imaging activities between the patients with normal and hyposensitive rectum during SNS stimulation. It is also unknown whether longstanding constipation is associated rectal hyposensitivity.

Conclusion
This was a pilot study with limited sample size. There is a early indication in the findings that RBD study threshold markers may predict the outcome of SNS treatment in patient with constipation. The RBD testing is simple and can be considered as a suitable pre-assessment tool when considering patients with constipation for SNS treatment.

COMMENT: Please note this study was a mini test as of part of a BSc degree project in evaluating SNS predictive factors in patients with constipation and faecal incontinence (the BSc project is offshoot of major MD/PhD projects which gained ethical approvals of the local trust’s R&D unit, Harrow Research Ethics Committee and ICREC). A clinical trial with larger sample size is required to confirm the current findings.