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Obstetric anal sphincter injuries: Review of recent medico-legal aspects

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Introduction

Obstetric anal sphincter injuries (OASIS) are the leading cause of anal incontinence in women and are increasing in incidence.[1] The NHSLA 10-year report[2] on maternity claims identified perineal trauma as being the fourth highest indication for claims, with £31 million in legal pay-outs alone.

OASIS could be classed as moderate to severe harm in the National Patient Safety Agency (NPSA) stratification (http://www.npsa.nhs.uk/corporate/news/npsa-releases-organisation-patient-safety-incident-reporting-data-england/). There are also initiatives to declare it as a patient safety indicator (www.oecd.org/dataoecd/53/26/33878001.pdf).

More recently, in *Davison v Leitch*[3] EWHC 3092, a High Court Judge awarded £1.6 million in damages where the breach of the duty of care included failure to comply with national guidelines (NICE, Royal College of Obstetricians and Gynaecologists (RCOG)) to perform an episiotomy which was adequately angled away from the anal sphincter muscles (mediolateral episiotomy). Other findings included a failure adequately to diagnose the injury, inadequate post-operative care, failure to inform the patient and her general practitioner about the condition and inappropriate use of forceps.

Given the potentially devastating physical injuries suffered by the patients and the financial loss to the NHS when OASIS arises, this is an issue which demands careful attention from the medico-legal community.

Prevention

Since the judgment in *Davison*,[3] RCOG have published revised guidelines on the management of third- and fourth-degree perineal tears.[4,5] It includes recommendations for evidence-based interventions to prevent OASIS.

The RCOG have recommended that episiotomy should be performed at a 60° angle to the midline at the time of cutting, when the perineum is distended. This is an evidence-based recommendation and hence it is worthy of note that the relevant section in the NICE intrapartum guideline was not revised in their latest update. The NICE intrapartum guidelines continue to recommend an episiotomy at 45°–60° at the time of cutting. As set out above in the RCOG guideline, a 45° angled episiotomy places it at a post-delivery suture angle of less than 30°, which has been shown to increase the risk of OASIS.[6–10]

Both the RCOG[4] and NICE[5] continue to recommend mediolateral episiotomies for instrumental deliveries. The RCOG guideline[4] also recommends a 'hands-on' approach on the perineum at the time of birth as opposed to a 'hands-off' or a 'hands-poised' approach.

The recommendation from the RCOG guideline based on a Cochrane review is to use warm perineal compresses during the second stage of labour.

While standardised approaches are available to achieve correct episiotomy angles (using special scissors that are fit for purpose) and perineal protection techniques (with evidence-based clinician training), the optimum temperature for warm compresses remains to be standardised.

Role of national guidelines

Should a failure to follow the nationally recommended preventative intervention guidelines be regarded as a breach of the clinician's duty of care?

The arguments in favour and against codifying all breached of duty in clinical negligence cases by treating national guidelines as sacred have been well rehearsed over the years. For instance, it has been suggested national guidelines should serve to define the standard of care.[11] However, to date the Courts have resisted giving guidelines anything akin to legislative status.

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Indeed, guidelines are still regarded as an indication of current thinking in English law. Nevertheless, they are taken seriously by the courts, especially where following them would minimise patient harm.

Taking a somewhat broad brush approach, the current situation can be summarised as follows: Guidelines will be an important piece of evidence for the Court to consider in any clinical negligence case. Where the relevant guidelines were followed by the treating clinician, a Court will be extremely slow to find any breach of duty. Indeed, absent any issue with the consenting process, it would be very rare to find a clinician in breach of duty where the relevant NICE or RCOG guidelines had been followed. On the other hand, a failure to follow the relevant guidelines, although not in itself determinative of negligence, will be highly persuasive and will require a satisfactory explanation by the clinician of the reason why they were not followed. Any clinician who has failed to adhere to national guidelines and does not have a reasonable explanation for his/her actions will be inviting the court to uphold the allegations of negligence.

In the arena of obstetric medicine, if recommended preventative measures were not carried out during the delivery process and the patient incurred OASIS, expert testimony will remain the basis for establishing whether deviations are acceptable practice. It will be interesting to see if there are any 'contrary and logically defensible' opinions that might be considered as reasonable justifications by the courts for failing to follow the new RCOG guidelines.

Perhaps one of the most cogent arguments against the promotion of the guidelines to the position of legislative authority on breach of duty is made by the current divergence in the two written guidance documents in this very area of medicine. As is set out above, the NICE guidelines conflict with the RCOG guidelines for the degree of the angle for an episiotomy. Given that compliance with the NICE guidelines would include performing an episiotomy at 45°, an angle shown to increase the risk of OASIS (as discussed above), there is plainly an argument that mere compliance with the NICE guidelines should not exonerate a treating surgeon who has adhered to the NICE guidelines but not to the RCOG guidelines. Indeed, the RCOG guideline is more reflective of current thinking and based on the latest evidence. Untangling this mess will remain the duty of the liability expert until the NICE Guidance is amended.

Impact of the 'Montgomery' judgement

The recent Supreme Court Judgment in *Montgomery v Lanarkshire Health Board*,[12] on consent arguably replaces medical paternalism with patient autonomy. It highlights the importance of counselling patients adequately about treatment options, the need clearly to explain the material risks of any recommended procedure alongside the risks of not proceeding with the recommended procedure and the need to explain all reasonable alternative procedures available. Only these explanations will allow the patient to make an informed decision as to their care. The disclosure of risk should be determined by whether *the patient* would attach any relevance to the risk.

Montgomery, whilst not an OASIS case, concerned the advice given (or in that case not given) about the risks of shoulder dystocia in a diabetic mother. It was held as a fact that had the mother been provided with appropriate advice she would have elected to have a caesarean section and her child would, on the balance of probabilities, not have sustained the injuries that eventuated in the course of labour.

Informed consent/disclosure of risk

Paragraph 82 of the *Montgomery* judgment interpreted this as:

> duty of care to avoid exposing a person to the risk of injury, which she would otherwise have avoided, but it is also the counterpart of the patient's entitlement to decide whether or not to incur that risk.

Paragraph 84 stated:

> Furthermore, because the extent to which a doctor may be inclined to discuss risks with a patient is not determined by medical learning or experience, the application of the Bolam test to this question is liable to result in the sanctioning of differences in practice which are attributable not to divergent schools of thought in medical science, but merely to divergent attitudes among doctors as to the degree of respect owed to their patients.

Traditionally, the benchmark for assessing clinical negligence in a case involving the duty to disclose the risks of the proposed treatment has been the Bolam test. Paragraph 86 which stated:

> ... There is no reason to perpetuate the application of the Bolam test in this context any longer.

The Supreme Court therefore concluded that the Bolam test was not appropriate in consent cases stating at paragraph 87 that:

> An adult person of sound mind is entitled to decide which, if any, of the available forms of treatment to

> undergo, and her consent must be obtained before treatment interfering with her bodily integrity is undertaken. The doctor is therefore under a duty to take reasonable care to ensure that the patient is aware of any material risks involved in any recommended treatment, and of any reasonable alternative or variant treatments. The test of materiality is whether, in the circumstances of the particular case, a reasonable person in the patient's position would be likely to attach significance to the risk, or the doctor is or should reasonably be aware that the particular patient would be likely to attach significance to it.

Paragraph 94 emphasises the importance of disclosure of risks. It stated:

> No woman is likely to face the possibility of a fourth degree tear, a Zavanelli manoeuvre or a symphysiotomy with equanimity.

Much has been written about the impact on *Montgomery*[12] generally and it was undoubtedly a significant development in the law of clinical negligence; however, it is important to remember what it did not change as much as what it did. Significantly, it was recognised that there were still circumstances where a doctor could reasonably withhold information such as where the disclosure would be seriously detrimental to the patient's health or where the doctor was unable to confer with the patient as a result of the emergency of the situation or if a patient was unconscious (paragraph 88).

To apply *Montgomery* in case of OASIS, it is important to note that *Montgomery* does not mean that all doctors must explain the theoretical risks of OASIS in every case. As Hale LJ observed

> that is not necessarily to say that the doctors have to volunteer the pros and cons of each option [vaginal delivery or caesarean section] in every case, but they clearly should do so in any case where either the mother or child is at heightened risk from a vaginal delivery.

Applying *Montgomery* to OASIS cases

Whilst at present, there are no validated scoring systems that can predict an individual's risk of sustaining OASIS, it is suggested that in a case such as *Montgomery* where the mother was of small stature and the baby was larger than normal, amongst the risks to the child the doctor should also discuss the risks to mother of OASIS.[13]

The questions which the lawyers will ask when assessing the issue of negligence in an OASIS outcome consent case would be:

(a) Has the patient been provided with adequate information on the risks of OASIS in the circumstances?
(b) What would she have done if advised about the risk of sustaining OASIS in her particular case, and its consequences?

We warn that the impact on OASIS cases following *Montgomery* should not be overstated because in many instances, the decision to perform episiotomies or to use forceps will be decisions made in urgent or emergency situations where obtaining consent may not be reasonably possible, at least from the woman who is giving birth.

Causation

The application of Bolam to causation was addressed in paragraphs 96–105 of *Montgomery*. On the issue of causation, the Supreme Court found as a fact that had the risk of shoulder dystocia and its potential consequences been discussed with Mrs Montgomery then she would probably have opted to have a caesarean section. Thus, causation was established.

The case also made it clear that the Court was concerned with how the patient would have reacted to the risk of the specific condition rather than a general warning of risks of 'grave consequences'. In other words, where there is a risk of OASIS, the patient should have these risks explained. These risks include not just the risk of injury but the potential consequences of such injuries including anal incontinence.

Could the 'But for' principle be applied to preventative interventions recommended to reduce the risk of incurring OASIS? The 18% OASIS reduction demonstrated in a recently published two centre UK study using 60° angled episiotomy scissors is a case in point.[14] Whether it is compelling enough to invite allegations of disregard for patient safety remains to be tested.

Conclusion

OASIS can result in embarrassing and sometimes devastating consequences for women. The improvement in outcomes demonstrated when employing the preventative steps recommended in the RCOG guidelines is welcome. It is to be hoped that NICE will embrace similar recommendations in the near future.

It was feared that the erosion of the Bolam test in consent cases would lead to greater uncertainty in such

cases. Certainly, it is clear that the recent developments in the law relating to consent mean that patients are entitled to more advice and hence more choice than ever before.

If this information flow further reduces the instances of OASIS then it may be felt that uncertainty in litigation is a price worth paying.

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