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Laparoscopic Adjustable Gastric Banding: a miracle cure?

Obesity is the bane of modern times. Its ever-rising incidence and the frequent lack of success of conventional weight loss methods, has lead to the evolution of surgical weight loss techniques. Laparoscopic Adjustable Gastric Banding (LAGB) is one such procedure aimed at assisting in the loss of weight in obese individuals for whom traditional methods have failed

The *"obesity crisis"*

The comfortable lifestyle of the 21st century has brought with it some unique issues: in affluent societies, the abundance of food, lack of physical activity and busy routines, has resulted in the "*obesity crisis*". Obesity is a consequence of energy intake in excess of the body's requirements. It is usually addressed in two categories based on Body Mass Index (BMI) which is calculated as weight (kg) divided by the square of height (m^2). BMI of 25 to less than 30 is considered *overweight*, and a BMI greater than 30 is identified as *obese.*

According to the *Australian Bureau of Statistics*, in 2004-05 54% of all Australian adults i.e. 7.4 million people were either overweight or obese.[1] It has been estimated that in 2005, obesity and its associated illnesses cost Australian society and governments a total of $21 billion,[2] signifying that obesity not only has implications for the individual but also for the economy at large. In light of this, in July 2006, the Australian Government implemented a five year, $500 million program, the Australian Better Health Initiative, with a focus on healthy weight.[3] This was accompanied by a national action plan for the youth called *Healthy Weight 2008: Australia's Future, the national action agenda for children, young people and their families*, allowing the health sector, food industry and communities to work together to prevent obesity in the first place, and assist in weight management for those already affected.[4]

LAGB – the evolution

The latest intervention in the battle against the "obesity crisis" is Laparoscopic Adjustable Gastric Banding (LAGB). This is a bariatric (obesity-related) surgical procedure aimed at reducing the stomach capacity by placing an adjustable band around the upper end of the stomach in obese individuals for whom traditional methods such as exercise and diet control alone have proven to be fruitless weight loss strategies. LAGB has been around since 1982. It was developed by Austrian surgical researchers.[5] It replaced the non-adjustable gastric band, and was found to be a more effective weight loss tool than its predecessor. The first placement of a BioEnterics® LapBand® System (LAGB®) took place in 1993.[6] Since then, this procedure has helped scores of obese people achieve weight loss and reduce their risk of diseases such as diabetes, cardiovascular disease and cancer, all of which are associated with obesity.

LAGB – the procedure

The procedure is performed under general anaesthesia. Four to five small incisions are made on the abdominal wall and are used to pass a laparoscope (a flexible tube with a telescope at the end used to visualize the abdominal cavity), surgical instruments and the adjustable silicone gastric band into the abdomen. The silicone band is placed around the upper end of the stomach, creating a small pouch above the band.[7] This smaller stomach pouch re-

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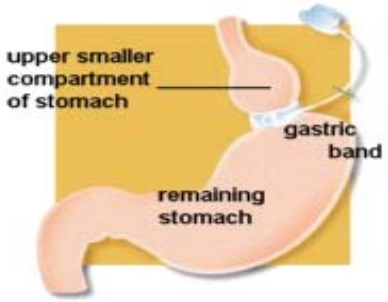
stricts the quantity of food consumed per meal and ensures satiety with smaller portions of food, thereby reducing the caloric intake of the patient and resulting in weight loss. The band is connected to a reservoir placed subcutaneously. Injecting fluid into or out of this reservoir can alter the circumference of the band and hence the degree of restriction. A tighter band places greater restriction on the stomach which lowers dietary intake.

This feature also allows for adjustment of the band according to the varying dietary needs of the patient throughout life. For example, during pregnancy the band can be loosened to accommodate the increased nutritional requirements. This adjustability adds to the appeal of the device. The procedure is less invasive than conventional methods as smaller incisions are used, reducing the risk of infection and other complications. Post-operative morbidity is reduced, and the patient is able to resume daily activities sooner.



Laparascopic Adjustable Gastric Banding [8]

Life after LAGB

Placing the band is in fact only one aspect of the weight loss process with major dietary and lifestyle alterations essential to complement the procedure. The recommended diet following a LAGB procedure consists of mainly liquid and puréed food in the first few weeks after the procedure, with the consistency gradually returning to normal over a couple of months. Patients are encouraged to eat small frequent meals, increase chewing time, avoid drinking during the meals, abstain from snacking between meals, avoid foods with a high sugar content, exercise for at least 30 minutes a day and also otherwise maintain an active routine.

These dietary alterations necessitate very real changes in lifestyle and should be thoroughly considered before the decision regarding the surgery is made as the resolve and commitment of the individual and availability of the support required, have far reaching implications on the success of the procedure and the achievement of weight loss.

Safety and efficacy

Despite all its modern safety features, laparoscopic banding is after all a surgical procedure and requires the same post-operative caution and care associated with any conventional surgery. The rates of complications reported in various studies since the advent of the procedure are relatively low. ASERNIP-S (Australian Safety and Efficacy Register of New Interventional Procedures – Surgical), an office of the Royal Australasian College of Surgeons dedicated to providing assessments of emerging surgical techniques and procedures, identified the overall morbidity rate associated with LAGB to be as low as 2.6%.[9] However, there are numerous determinants of the outcome including: the skill and experience of the surgeon, quality of equipment, aseptic measures, quality of post-operative care and most importantly the commitment and cooperation of the patient.

Even though the weight loss at four years of follow-up associated with LAGB is not significantly different from conventional bariatric procedures such as Roux-en-Y Gastric Bypass (RYGB),[10] nonetheless its lower rates of post-operative morbidity and mortality make it the preferred procedure in most cases in Australia. Post-LAGB data is only available for up to 8 years, and there is need for longer follow-up studies to add to the body of knowledge regarding the efficacy and long-term benefits of the procedure. [10]

Effect on co-morbidities

Surgically-assisted weight loss has a great impact on the quality of life of the individual. The most immediate advantage in this regard is the reduction in co-morbidities such as diabetes, hypertension, dyslipidemia (abnormal blood lipid profile), asthma, polycystic ovarian syndrome and even depression, all of which are highly correlated with obesity.

It has been documented that blood glucose and insulin levels in more than two-thirds of type 2 diabetics have returned to their pre-diabetic state removing clinical evidence of the disease.[11] Thus surgically-induced weight loss has resulted in remission of diabetes. Insulin resistance and pancreatic beta cell function have also shown improvement.[12] This discovery has long term implications for those struggling not only with morbid obesity but also diabetes and its attendant complications.
The other major disease entities associated with obesity, hypertension and dyslipidemia, have also shown remission and better control in the form of reduced medications, after LAGB.[10] Polycystic ovarian syndrome, one of the major determinants of fertility among women, also showed resolution following the procedure.[10]

Benefits of bariatric surgery surpass medical gain with psychological aspects also showing remarkable improvement. Depression and other mental disorders are relatively common among obese individuals, undoubtedly owing to the social prejudice associated with the condi-

tion, and weight loss improves social persona and increases self-esteem and confidence, thereby improving quality of life. LAGB has had a significant effect in the reduction of depression.[10]

Not for everyone

Despite the benefits of bariatric surgery, it is not for everyone. Satisfaction of a range of patient selection criteria is usually required. Some of the criteria considered to assess eligibility for LAGB are: [10]

- BMI greater than 35 kg/m^2.
- Presence of significant medical, physical or psychosocial problems associated with obesity.
- History of extensive unsuccessful efforts to relieve those problems by non-surgical means.
- Complete understanding of the role the individual must play to ensure success and realistic expectations of the outcomes.

LAGB for adolescents

Obesity has not only dramatically increased in recent years for adults. It is also increasing at alarming rates among adolescents. According to one estimate, one in five Australian children and adolescents are either overweight or obese. An informed estimate states that in the next decade approximately 65% of young individuals will become overweight or obese.[13]

In the face of this crisis, LAGB with its high safety and efficacy level along with the features of adjustability according to changing dietary needs and reversibility of the procedure provides the ideal solution for successful weight loss in obese adolescents for whom the conventional weight loss techniques have been unsuccessful. The added advantage of beneficial effects on comorbidities also adds to the appeal of the procedure for young people. Nadler et al. in their paper on experience of LAGB in paediatric patients comment that, "It remains, in our opinion, the optimal surgical option for paediatric patients with morbid obesity".[14]

Food for thought

As LAGB is a novel surgery, optimal surgical and postoperative patient care procedures are still undergoing evolution.[14] This raises a number of challenges associated with widespread prescription and performance of LAGB, such as adequate training for surgeons, workload division to ensure better technique, reduction of complications and revisional procedures,[10] an effective and accessible postoperative patient care system and research into ways to improve the existing methodology.

Aside from these challenges, there are a number of ethical considerations. For example, patient selection for the procedure should be a decision based on the selection criteria mentioned above and not on commercial benefits for the clinics. However, the criteria are relatively subjective and compliance with them relies on the physician's discretion. This is of special consideration in the case of adolescents for whom the procedure necessitates quite drastic lifestyle adjustments. These adolescent cases thus need greater assessment of risk vs. benefit as compared to adults. A decision for bariatric surgery must be the very last resort in the battle against obesity. It should only be considered after all conventional weight loss measures have been exhausted - for all ages but more so for adolescents.

The surgical technique and equipment also warrant consideration as the outcome of the surgery relies heavily on them. They should be of the highest standard. Most crucially, specialized post-operative care must be available and easily accessible. It is also of utmost significance that the individual have complete understanding of the risks and possible complications and how to avoid them: this can be assured with proper counselling to facilitate informed decision-making.

Due to its safety, efficacy and beneficial effects on comorbidities, LAGB should be made available to all those eligible through an equitable health system. O'Brien et al in their paper on weight loss and bariatric surgery write "We should recognise that obesity remains one of the last areas in which discrimination is regarded as acceptable".[15] This highlights that the most vulnerable populations must be provided this service without affordability constraints thereby demanding government funding and support. This initiative in the long term can significantly reduce obesity-related health expenditure, with better resource utilization

Conclusion

Though it seems to be the miracle cure for morbid obesity and is a ray of hope for those afflicted with this disease, LAGB does come at a price. The role of the individual in determining the success of the procedure cannot be overemphasized, and a complete understanding and acceptance of the physical and psychological challenges involved are crucial for informed decision-making. Bariatric surgery is a life-long commitment and requires diligent and persistent commitment by the individual demanding a complete modification of lifestyle in order to achieve and maintain the desired weight loss and prevent complications.

In light of this discussion we re-visit the time-worn phrase, "prevention is better than cure", and we realize that nothing can replace a healthy diet and regular exercise throughout life, to prevent us from having to contemplate such drastic weight loss measures and their implications not only for individuals but also for the whole society.

ENDNOTES

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Australian Research Code

This article explores the new Australian Code for the Responsible Conduct of Research.

After more than three years of consultation and discussion, the *Australian Code for the Responsible Conduct of Research* (referred to here as the *Code*)[1] was released in August 2007 by the National Health and Medical Research Council (NHMRC), the Australian Research Council (ARC), and Universities Australia (previously known as the Australian Vice-Chancellors' Committee or AVCC). It replaces the 1997 *Joint NHMRC/AVCC Statement and Guidelines on Research Practice* (referred to here as *Statement and Guidelines*).

The *Code* is addressed to research institutions and researchers. It charges research institutions with the responsibility to develop and maintain a framework of research governance "through which research is assessed for quality, safety, privacy, risk management, financial management and ethical acceptability." (*Code*, 1.2.1) This requires the development and ongoing revision of written policies in all these areas – tasks which many research institutions are currently undertaking.

It also alerts research institutions to their duty to provide their researchers and research trainees with both induction and ongoing education about research ethics and institutional policies. And it alerts researchers and research trainees to their duty both to learn about and adhere to these standards.

Statement and Guidelines contained just over three thousand words. The *Code* is about four times that length. It does not in any place either contradict the earlier document or reverse its basic direction. Instead, the *Code* elaborates and expands the earlier statement.

After a brief introductory Statement, the 1997 document details seven Guidelines for good research practice. The *Code* contains two main parts. The first, Part A, includes six of these guidelines as well as two others. It is titled 'Principles and Practices to Encourage Responsible Research Conduct.' The second part of the *Code*, Part B, elaborates the final guideline from the 1997 document. It is titled 'Breaches of the Code, Research Misconduct, and the Framework for Resolving Allegations.' The *Code* also contains a short introduction, and three short appendices.

Part A. Responsible research conduct

All eight sections in Part A of the *Code* detail the responsibilities of both institutions and researchers. This recognition of different but complementary responsibilities reminds us that responsibility for the ethical conduct of research does not rest solely on some subset of the research community, but rather imposes duties upon all.

The first of these sections details general principles for

responsible research. The focus is on the research culture of each institution. This makes good sense, because the environment in which we work is extremely influential in bringing out either the best or the worst which is within us. In various ways, institutions must foster and "maintain a climate in which responsible and ethical behavior in research is expected." (*Code*, 1.1) This includes "induction, formal training and continuing education for all research staff…[in] research methods, ethics, confidentiality, data storage and records retention, as well as regulation and governance." (*Code*, 1.3) It also includes effective mechanisms for mentoring and supervision. Institutions must also support their research culture through good governance and management practices. Significantly, one of the responsibilities of researchers is to report possible research misconduct in a timely fashion. (*Code*, 1.11)

The second section in Part A of the *Code* considers management of research data and materials. In general, data and materials from published research should be retained and accessible for at least 5 years, while data from clinical trials should be kept 15 years or even longer. Beyond that, some data and materials should be retained "for as long as interest and discussion persist" (*Code*, 2.5.1), and some things with "community and heritage value… should be kept permanently." (*Code*, 2.1.2)

The next section is about the supervision of research trainees. As well as detailing responsibilities for institutions and experienced researchers, this section also charges research trainees with the responsibility of seeking guidance.

Section 4 is on the publication and dissemination of research findings. It stresses the responsibility of researchers to disseminate all research findings, including "negative findings and results contrary to their hypotheses." (*Code*, 4.4.1) It encourages responsibly communicating research findings in the public arena (*Code*, 4.12).

Section 5 is on authorship. Authoring papers – and particularly, being first author – are very important to researchers' careers. This section reflects this importance by providing detailed rules about authorship. Authorship must be based on "substantial contributions" to the "conception and design of the project," the "analysis and interpretation of research data," *and* "drafting significant parts of the work or critically revising it." On the other hand, providing materials, giving routine technical support, or being the head of the department does not qualify someone as an author. The *Code* asks that researchers appropriately acknowledge the contributions of, for example, research assistants and technical writers. (*Code*, 5.6)

The final three sections of Part A are about peer review, conflicts of interest, and collaborative research across institutions. The first and third of these are new topics that were not addressed in the 1997 document. The *Code* asks institutions to encourage peer review, and exhorts researchers to participate in it. Noting that conflicts of interest are "common," it stresses that "it is important that they are disclosed and dealt with properly." (*Code*, 7.1) Research across institutions requires comprehensive written agreement. Even when conducting research outside Australia, "researchers supported by Australian public funding should make every effort to comply with this Code." (*Code*, 8)

Part B. Investigating research misconduct

The *Code* distinguishes between research misconduct and mere breaches of the *Code*. (Catholics might think of this as analogous to the distinction between mortal and venial sin!) Research misconduct is serious or deliberate deviation from the *Code*. It typically involves all three of the following: (i) a breach of the *Code*; (ii) "intent and deliberation, recklessness or gross and persistent negligence"; and (iii) "serious consequences, such as false information on the public record, or adverse effects on research participants, animals or the environment." (*Code*, 10.1) Examples of research misconduct include "fabrication of results," "falsification or misrepresentation of results," "plagiarism," "failure to declare and manage serious conflicts of interest," "conducting research without ethics approval," "failure to follow research proposals as approved by an ethics committee," "risking the safety of human participants, or the wellbeing of animals or the environment," "deviations from this Code that occur through gross or persistent negligence," and "wilful concealment or facilitation of research misconduct by others." (*Code*, 10.1-2) Breaches, on the other hand, are less serious deviations from the *Code*, such as errors that are minor or unintentional.

Breaches may be remedied within the department or institution by counselling or advice. The *Code* requires that "full records of the process must be kept," and cautions that "failure by supervisors or heads of departments to address issues properly may in itself represent misconduct." (*Code*, 11.2) It also cautions that the "repetition or continuation" of such breaches "may constitute research misconduct" and "lead to more serious consequences." (*Code*, 11.1)

Allegations of research misconduct require a more serious response, and the *Code* sets out the process for this. (Again, Catholics will note similarities between this process and both the process to investigate allegations of abuse set out in *Towards Healing*, and the process to investigate allegations of professional misconduct set out in *Integrity in Ministry*.[2])

The *Code* requires institutions to appoint both one or more "advisers in research integrity," and a "designated person" to conduct a preliminary investigation of allega-

tions of research misconduct. Anyone with concerns about any research within the institution should speak to one of the advisers. After considering options with them, they may address a written allegation of research misconduct to the designated person. The designated person conducts a preliminary investigation, and then reports to the CEO. If the researcher admits misconduct, less serious cases can be resolved through negotiation with all parties. On the other hand, both more serious and disputed cases of misconduct should proceed to a research misconduct inquiry. In these cases, the CEO must decide between an internal institutional inquiry and an independent external inquiry. The *Code* gives guidelines for the membership and processes of each type of inquiry. Also, it "does require institutions to establish independent external research misconduct inquiries to evaluate allegations of serious research misconduct that are contested." (*Code*, 9.3)

If misconduct is proven, erroneous information on the public record should be corrected. Disciplinary action may also be warranted. "Serious misconduct in research can lead to serious penalties, including termination of employment." (*Code*, 10.1) However, particularly with external inquiries, "the person subject to the inquiry may have an entitlement to appeal to a higher authority, most usually the courts." (*Code*, 12.3)

Comments

Firstly, the call for institutional research governance in both the *Code* and the new *National Statement* holds promise to remedy a significant problem which has emerged in Australian research ethics. In recent times, too many institutions have expected their Human Research Ethics Committee (HREC) and its secretariat to cover every aspect of research governance. Further, they have required this without adequately resourcing their HREC. This reminder about institutional research governance and the roles of both institutions and researchers in research ethics is at once "our best opportunity to improve the functioning of the HREC system" and "potentially the most significant advance in the Australian research ethics environment for several years."[3] Provided only that institutions heed the call,[4] it could "herald a new era in the governance of research involving humans in Australia."[5]

Secondly, we should not dismiss the issue of research misconduct. While the number of proven cases of serious misconduct is still small (*Code*, 9.3), there are informed suggestions that the number of unreported cases is not small, and that the occurrence of serious offences may be increasing.[6] The focus on research misconduct in the *Code* is therefore both appropriate and timely.

Thirdly, there is considerable debate about the relative merits of internal and external inquiries. There are benefits to both. For example, an institution may be more willing to initiate an internal inquiry, and such an inquiry may be more sensitive to context within the institution. On the other hand, an external inquiry may well prove to be more objective, and its independence from the institution will reassure the public that it's not a whitewash. In the United States, the Office of Research Integrity oversees all federally-funded research.[7] As well as providing education to promote research integrity, its functions include advising and providing technical assistance to institutions responding to allegations of misconduct, and monitoring and reviewing research misconduct investigations. While many commentators have called for a similar body in Australia, the *Code* notes that "many steps are required to create it, and complex issues in the Australian constitutional and other legal environments must first be addressed." (*Code*, 9.3) While experience is gained with the new Code, the NHMRC "intends to study whether, and how, a national independent enquiry system might work."[8]

Fourthly, as our procedures for investigating research misconduct continue to develop, a process of appeal against the decisions of inquiries must be set out. Whereas the Catholic Church's *Towards Healing* does articulate a process of appeal and review, the current *Code* states only that "there should be an avenue for the findings to be appealed." (*Code*, 10.4) As experience is gained with the *Code*, this process of appeal must be more clearly articulated. For example, this might be one role for an independent national body.

Fifthy, while the *Code* recommends ethics training for researchers, it does not require this for NHMRC funding. By contrast, in the United States, applicants for funding from the National Institutes of Health (NIH) must document that they have completed ethics training.[9] Will the *Code*'s recommendation be sufficient to cause Australian institutes to provide ethics training, and Australian researchers to undertake this? If not, a requirement like that of the NIH may have to be considered.

Sixthly, it is obviously in the best interests of both institutions and researchers to have ethics training. All too often, the path to serious misconduct begins with small steps, as researchers either do not know proper standards or choose to ignore them at first in small matters. Ethics training will help to develop a research culture where even these small, first steps do not occur, nipping in the bud a potent source of research misconduct. Ultimately, our focus must be not on managing research misconduct but on preventing it.[10] Prevention is much better than cure, and ethics training is a great place to begin.[11]

ENDNOTES

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Preventing Pregnancy After Rape

This article explores what may ethically be done to prevent pregnancy after rape.

The Church teaches that sexual intercourse should be something freely chosen by each of the partners. This freely-chosen act should both express and deepen love, and be open to procreation. This is why marriage is the only proper place for sexual intercourse. This is also why the Church forbids contraception except in the special case of rape.

In rape, the person assaulted does not freely choose to have sex. Nor is rape in any way an act of love. Instead, rape is simply an unjust assault. Any sperm in the woman's reproductive tract is therefore present only because of an unjust assault. And since the seventeenth century, the Church has taught that in this special case a woman is entitled to use contraceptive measures to protect herself from pregnancy, which would simply continue an unjust assault.

The *Code of Ethical Standards for Catholic Health and Aged Care Services in Australia* articulates this general principle more precisely. After rape, it explains, a woman may use contraceptive measures, but she may not use abortifacient ones. Thus, as it discusses the "care of persons who have been sexually assaulted," the *Code* permits "measures designed to prevent ovulation or fertilisation," but forbids "interventions aimed at causing abortion." (II.3.9)

What might be done? In the past, doctors used a vaginal douche, an intrauterine douche, or dilation and curettage (D & C) to try to clean any sperm away. These methods are ineffective and no longer used. A Catholic would not use the drugs mifepristone (RU486) or danazol, or an intrauterine device (IUD), all three of which are abortifacient. From the mid-1970s, the Yuzpe regimen was widely used. More recently, this has largely been superseded by the use of a progestin called levonorgestrel (LNG). Usually, 0.75 mg of LNG is taken as soon as possible after the rape, with another 0.75 mg taken 12 hours later. This is more effective than the Yuzpe regimen, as well as less likely to cause nausea and vomiting.

Three competing practical guidelines

The general principle above must be expressed as a practical guideline. Surprisingly, there are three rival positions. Firstly, there is the "pregnancy approach." This approach requires only pregnancy testing before LNG might be given. Pregnancy cannot be detected until about ten days after conception, so this test will not detect a child conceived through the rape. However, it could detect an existing pregnancy. In this case, because an already pregnant woman cannot become pregnant again through the rape, the LNG is unnecessary and should not be dispensed. In every other case, the woman is given LNG.

Secondly, there is the "ovulation approach." As well as pregnancy testing, this approach also requires ovulation testing. The exact testing varies: the Peoria Protocol requires both urine and blood testing;[1] another protocol requires only urine testing.[2] Again, LNG is not given if the pregnancy test is positive. As well, LNG is not given if the ovulation tests suggest either that the woman has just ovulated, or is immediately on the way to ovulating. In every other circumstance, the woman is given LNG.

Finally, there is the "no treatment approach." Advocates of this position hold that Catholics and Catholic institutions should not use LNG at all after rape. In their judgment, "the provision of hormonal emergency contraception under any conditions" is inconsistent with Catholic standards.[3]

Medical accounts and ethical arguments

Why are there three such different guidelines? There are two reasons. Firstly, advocates of these different approaches have different accounts of the action of LNG.

And secondly, they make different ethical arguments. We will look at each area. Beforehand, however, we will note what is known about the menstrual cycle and the development of pregnancy:

In the early part of a regular, 28-day menstrual cycle, one (or sometimes more) follicles develop in the woman's ovaries. About 2 weeks into the cycle, the pituitary gland in the brain secretes luteinizing hormone (LH). This LH surge causes the follicle(s) to develop rapidly, with ovulation occurring about 24 to 48 hours later. Ova can survive for only 12 to 24 hours, so sexual intercourse more than 24 hours after ovulation cannot lead to conception. On the other hand, sperm can survive in the woman's reproductive tract for up to 5 days (or perhaps slightly longer), so sexual intercourse up to 5 days (or perhaps slightly longer) before ovulation can potentially lead to conception. Fertilization or conception is a process that takes about 24 hours. New life is not present until the end of this process when the genetic material from the sperm and the ovum are united. Fertilization takes place in the fallopian tube near the ovaries. The conceptus takes 4 or 5 days to travel down the tube, and implants into the wall of the uterus or womb another 1 or 2 days later. On the other hand, if there is no pregnancy, the cycle continues with menstruation beginning about two weeks after ovulation.

Within these processes, there are two aspects of LNG's action about which almost everyone agrees. Firstly, it has no effect on an embryo which has already implanted into the womb. And secondly, the primary effect of LNG is to prevent or postpone the LH surge and therefore to prevent or postpone ovulation. To do this, it must be taken before or at least close to the LH surge. Even then, it is not always successful. Estimates of LNG's efficacy in preventing pregnancy range from about 60 to 90%.[4] It is most effective when taken within the first 12 or 24 hours after sex. While it may have some effect for up to 5 days, its efficacy falls away progressively and substantially over the first 72 hours.

Apart from that, there are three rival accounts of the other effects of LNG. It has long been known that LNG given at any stage of the menstrual cycle has some effects on the endometrium or inner lining of the uterus, and that these effects persist for days. The first account holds that these changes interfere with the implantation of the embryo into the womb. As an embryo that does not implant cannot survive, such an effect would be abortifacient. This first account, then, holds that LNG given before ovulation could have a contraceptive effect by suppressing ovulation, an abortifacient effect by eventually preventing implantation, or no effect at all; whereas LNG given after ovulation could either have an abortifacient effect or no effect at all.

This account of the other effects of LNG underpins both the no treatment and ovulation approaches, which use this same account in different ethical arguments. The no treatment approach argues that the possibility of an abortifacient effect can never be absolutely excluded, and therefore that LNG should never be used. On the other hand, while the ovulation approach holds that LNG cannot be used after ovulation because, they say, its only possible effect would be abortifacient, its advocates offer various ethical arguments to support its use before ovulation. For example, they might employ the Principle of Double Effect, or analyse the traditional three fonts of Catholic morality. They conclude that it is acceptable to give LNG before ovulation when "the drug acts only as an anovulant in the majority of cases and may or may not have an abortifacient effect in the remainder."[5] They therefore advocate ovulation testing to distinguish between the acceptable time to give LNG (i.e. before ovulation), and the unacceptable time after that.

The pregnancy approach is based on a different account of the other effects of LNG. This account is set out, for example, by Anna Glasier, who writes:

> Some have demonstrated minor changes in the endometrium which, the authors speculate, may be sufficient to inhibit implantation. However, the group with the greatest expertise and track record in research on the endometrium were unable to demonstrate any effect which might be associated with the inhibition of implantation.[6]

Noting that LNG seems to have effects beyond inhibiting ovulation, she suggests "other possible mechanisms" including "inhibition of fertilization."

Advocates of the pregnancy approach believe therefore that even after ovulation LNG works primarily through contraceptive effects such as the inhibition of fertilization. If there is an effect on implantation, they hold that it is "only relatively minor and secondary."[7] Their ethical arguments about the moral acceptability of LNG extend therefore to the time after ovulation as well as the time before it. This is why they do not require ovulation testing.

Lastly, there is a third account of the effects of LNG. In recent years, Horacio Croxatto and his colleagues have published research which suggests that the only significant effect of LNG is its suppression of ovulation. They argue that this mode of action "fully accounts" for its contraceptive effects, and therefore that it has "little or no effect on postovulation events." Previous calculations which implied a postovulatory effect, they suggest, were very probably based on inaccurate data. They base their own arguments on animal studies with rats and cebus monkeys as well as their own research with human beings.[8] This recent research has yet to be fully considered in the debate about preventing pregnancy after rape.

I offer four comments. Firstly, it is increasingly likely

that LNG does not affect implantation. Recently, the Catholic bishops of Connecticut decided– albeit reluctantly and under pressure – to change the protocol in their hospitals from the ovulation approach to the pregnancy approach. It is significant that even critics of this decision argued not that LNG does affect implantation, but only that it "might."[9] And, of course, if the latest research is correct, this is even stronger support for the pregnancy approach.

Secondly, there are difficulties with the ovulation approach. Even using both the urine and blood tests, there are sometimes difficulties in interpreting the results, and both false positives and false negatives. At a time when any delay may reduce the effectiveness of LNG, the blood test even in the best case scenario will take several hours. Even advocates of the ovulation approach admit that sometimes this test "cannot be done in an appropriately timely manner" and therefore "may not be feasible."[10] But on the other hand, "the value of the urine test is debatable in the absence of the corroborating data supplied by the blood test."[11] Finally, it is not clear how much difference this testing makes. In his blog, Bishop William Lori of Bridgeport CT commented that in 2006 "nearly 75 rape victims" were treated in Connecticut Catholic hospitals using the ovulation approach, and "no one was denied" LNG as a result.[12] It seems a lot of fuss for very little practical difference.

Thirdly, the ovulation approach sets a standard that is higher than that used elsewhere in medicine. For example, it is known that X-rays can harm a child in utero. However, when women of child-bearing potential come for an X-ray, all that is done is a pregnancy test. Given that the risk there is certain and the risk here is now questioned, it seems unreasonable to demand a higher standard of testing before LNG is dispensed.[13]

Fourthly, there is growing support for the pregnancy approach. The US bishops' Committee on Doctrine and Pastoral Practices has concluded that protocols based on the pregnancy approach "do not violate" Catholic ethical standards.[14] On 27 September 2007, the Bishops of Connecticut stated: "To administer [LNG] pills in Catholic hospitals to victims of rape a pregnancy test to determine that the woman has not conceived is sufficient. An ovulation test will not be required."[15] We have already cited articles supporting the pregnancy approach by theologians Hamel and Panicola, and Daniel Sulmasy. Finally, at the practical level, in 2002, the then President of the Catholic Health Association of the United States, Fr Michael Place, stated that while American Catholic hospitals follow either the pregnancy or the ovulation approach, the pregnancy approach is the "one most often followed."[16]

The issues discussed here are still controversial, which reminds us of the important place of individual decision-making. An individual woman who has been raped may prefer either not to take LNG, or to request ovulation testing. An individual hospital may still prefer to include ovulation testing in its protocol. In a hospital which follows either the ovulation or pregnancy approach, an individual doctor may choose to exercise conscientious objection. In the last two situations, a woman who has been raped must be told of the decisions that have been made and their implications, so that, if she wants to, she can seek treatment for pregnancy prevention elsewhere. But while allowing for these individual decisions, "it is safe to say that the pregnancy protocol may be followed in Catholic hospitals."[17]

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Kevin McGovern ✠

Emergency Medicine

Wide spread media newsprint articles suggest our emergency medical departments are in a state of crisis. The purpose of this article is to examine a snapshot of emergency medicine performance data to provide some context in which to respond to this issue.

Introduction

Recently, the Sydney Morning Herald reported the distressing story of a woman who endured a miscarriage in the toilet of a public hospital emergency department waiting room.[1] The story alerted the wider community to an alarming departure from accepted community expectations regarding standards of patient care. And yet an article of this nature is not an isolated occurrence. Both national and local newspapers consistently draw attention to alarming failures of emergency department care. Perusal of any number of recent newspaper articles easily demonstrates how the Australian public in general could assume that medical emergency department care is in a state of crisis. You need simply to glance at the headlines.

Role of media

In Australia we are privileged recipients of excellent news coverage. One of the great benefits of living in a democratic society is the ease with which diverse information for a range of purposes can be obtained. Characteristically Australian people like to be well informed. In relation to creating an informative repository for health knowledge, the media have certainly acquired significant responsibility in this regard. The Rodale Press Survey found that in America '39% of the respondents said they turn to TV for health and medical information, and 37% said they would ask a health professional.'[2] In Australia Walker and Jacobs similarly advise 'While certain members of the community have access to more authoritative sources of information…most community members only have the media for their information in this respect.'[3]

Not surprisingly, an American survey of editors and other executives confirms there is a widespread tendency by the media to sensationalise issues of importance.[4] Yet McGrath suggests that a real difficulty is posed for everyday people when sensitive topics of health are transcripted in a language of crisis.[5] Whilst grabbing our attention because the information is exciting or alarming, we can be left without a full balance of facts. Information that does not portray enough detail of either the culture or dynamics of the health care issue at hand, does not present a realistic picture.

The relationship between access to accurate information and community development is synergistic. With considerable ease, the parlance of language can either create opportunity for understanding and community learning, or misunderstanding, where issues are clouded through various distortions. It is particularly problematic for health care organisations when the media access data from authoritative sources but fail to present the data in the relevant context with the appropriate terminology. Consider for example, the 2003 news print coverage of the increasing violence facing hospital emergency departments in Melbourne.[6] Not unfairly, a news print article reported that violence by patients was increasingly a problem in hospitals across Victoria. To demonstrate this point the author identifies that '...at St Vincent's Hospital, staff made about 1000 code grey calls in response to aggressive behaviour from patients.'[7]

Whilst this data is accurate, there is not enough information to allow everyday people to interpret the relevance of the number of code grey activations by St Vincent's hospital. Dr Sansom, Acting Director, Emergency Medicine, St Vincent's Hospital comments that the number of code grey activations is a poor statistical indicator of the overall threat of occupational violence created by patients.[8] At St Vincent's Hospital an increasingly low threshold for behavioural disruption before a code grey is activated, and the pre-emptive category of planned code grey to manage 'potentially' aggressive behaviour, are two such variables that are needed to interpret the relevance of the number of code grey activations[9]. Subsequently the omission of such explanation contributes to an overly biased snapshot of data in this regard. The magnitude of such reporting not only shapes public perception and belief, but continues to politically motivate resource allocation at a time when strategic resource allocation is a critical issue.

Performance Measurement

Across Australia the impact of emergency department (ED) overcrowding on ED performance is an issue deserving widespread clarification. The extent to which all triaged patients are attended to within benchmarked time frames and the timeliness of patient transfers out of the ED are useful measures to consider when assessing the impact of increased demand. Several sources of aggregated national performance data for emergency medical care services are now available. The Australian Council on Healthcare Standards (ACHS) is the primary source of data here. The seven performance indicators used by the ACHS shed some light on quality issues such as whether the care given is accessible, safe, appropriate and responsive. All seven indicators are time based measures and in 2006 included voluntary responses from up to 217 organisations representing the public and private sectors.[10]

While this represents a large sample, we do not have access to further information to ascertain to what extent the sample is representative of the broad mix of emergency departments across metropolitan and rural areas.

Snapshot of performance

Across Australia 'in 2005-06 there were more than 6.3 million accident and emergency occasions of service in all hospitals.'[11] This represents an increased demand for emergency medical care, apprising '223 presentations to emergency departments per 1,000 weighted population' for that year.[12] The Australasian College for Emergency Medicine provide a point of comparison and report Australia has a lower annual rate of ED attendance than the USA and Canada.[13] In Australia a strengthened national framework for the analysis of performance data would be helpful to the industry .

Staff in overcrowded emergency departments face a number of challenges, including effectively attending to patient presentation for treatment in a time sensitive manner. Nationally, nurses use the Australian Triage Scale (ATS) to prioritise response times in accordance with assessed patient acuity and urgency. This includes the categories of resuscitation (ATS1), emergency (ATS2), urgent (ATS3), semi urgent (ATS4) and non urgent (ATS5).[14] A five point triage scale is considered a best practice standard internationally. Studies reveal 'that a 5-point triage scale is more effective than a 3-point scale in producing consistency of triage.'[15]

For the ACHS emergency medicine performance indicator, 'Waiting Time: Relative to Triage Category,' two issues are noteworthy. Firstly, for the aggregate of hospitals that voluntarily provided relevant performance data, only 2 of 7 performance indicators resulted in a desirable result.[16] ATS category 1 - immediate response required for resuscitation and Category 5 - response required within 2 hours, were the only indicators that adequately met the benchmarked timeframes.[17] Secondly, for the lower triage priorities of ATS, 3, 4 and 5 the performance by the participating health care organisations was also highly variable.[18] It is possible that the high variability in results for specific data sets may signify that definitions for the performance measures have not been interpreted consistently across the participating organisations.

The data provided by the ACHS for ATS 3 is now considered in more detail.[19] In 2006 across Australia an aggregate of 207 health care organisations were able to attend to ATS Category 3 patients within 30 minutes in 62.1% of all cases. This compares poorly to the benchmark, where it is expected that a minimum of 75% of patients will be seen within 30 minutes. When comparing the performance of states and territories, significant variations in performance become apparent. For Victoria, an aggregate of 27 organisations responded to 70.6% of patients within 30 minutes, while in South Australia this was managed for only 50.4% of patients by 19 organisations.

Nationally 20% of organisations performed very well and attended to ATS 3 patients in 30 minutes in 96.3% of all cases. If the performance of all health care organisations matched the rate of 20% of the best performing organisations, this would result in an additional 449,119 ATS 3 patients nationally, being attended to in the appropriate time. Focus on the worst performing organisations shows that nationally, 57 organisations had a total of 88, 692 fewer patients being responded to within 30 minutes, producing a much lower proportion of patients (47%) seen in the appropriate time, than the average rate of 62.1% of all patients. Considering ATS 3 is for patients with an urgent acuity with the degree of seriousness that translates into a 'potentially life threatening' condition, this is not good.[20]

The Australian Institute for Health and Welfare report that between 2001/02 and 2005/06 'The proportion of emergency visits by triage category remained fairly stable.'[21] This somewhat discredits the idea that increasing presentations by triage category 4 and 5 patients contribute to what is a seemingly poor national adherence to agreed benchmarks for performance. The Australian College for Emergency Medicine (ACEM) refutes the suggestion that patients assigned a 'semi urgent' or 'non urgent' triage category by the ED should have sought treatment through the primary health care system.[22] The ACEM refer to Ashby's (2001) research which shows significantly different rates of hospital admission between patients triaged at category 4 and 5 who attend an ED, and patients who consult their local Doctor. They state: 'Admission to hospital rates are higher for ATS 4 patients (~20 – 30%) and ATS 5 patients (~5- 10%) than for patients seen in general practice (<1%). (Ashby, 2001).'[23]

Bed block is widely cited to singularly have the most impact on the flow of patients from the emergency department into appropriate streams of acute inpatient care. Bed block refers to a shortage of available inpatient beds to which stabilised ED patients can be transferred, as a process of hospital admission.[24] The occurrence of bed block is measured by an ED patient length of stay greater than 8 hours by the ACHS.[25] Bed block also slows down the admission of patients into the ED from the waiting room, and is associated with adverse patient outcomes on a number of levels. A deterioration in performance for the indicator, 'Access Block, ED time exceeding 8 hours' from 2002 to 2006 is demonstrated by the increasing rate from 25% to 27.4% nationally.[26] The Australasian College for Emergency Medicine in their commentary on the ACHS indicator results commented that '…It is generally agreed that any Access Block greater than 10% is a major impediment to patient care and reflects a public hospital system under serious strain…'[27] If the 20th Percentile

rate for access block of 6.45% was achieved by all health care organisations nationally, this would generate an additional 114, 934 patients not adversely affected by the unavailability of hospital beds, a much better outcome for hospital accessibility.[28]

Performance in Context

There has not been the capacity to examine more than a brief and minimalist coverage of performance data here. The data indicates that whilst the term 'crisis' is too strong a word to describe the state of emergency medical care in Australia, there are obvious difficulties in terms of performance around the country. This is further reinforced by the obvious variation between the states and territories in meeting particular benchmarks. Whilst an analysis of national data can be misleading because it does not well inform what is occurring at the local level, the opposite is also true. Greater attention to the conformance of benchmark standards across Australia are crucial if the health system has any regard for whole of population accessibility, responsiveness, appropriateness and safety of the emergency department service. The performance of individual health care organisations importantly plays a role in informing the obtainability of the standard for the whole.

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