Welcome to the SEE Podcast, presented by the American Society of Anesthesiologists. SEE, translating emerging anesthesia knowledge for your daily practice.

Natalie F. Holt, MD: Hello. My name is Natalie Holt and I’m one of the members of the SEE Editorial Board. As many of you know, the SEE Program highlights emerging knowledge from recent literature covering a variety of topics relevant to your daily practice.

In SEE Volume 35B, we included a provocative article from the *European Journal of Anaesthesiology*. In October 2014, anesthesiologists at the Torbay Hospital Day Unit in Devon, England changed their preoperative fasting policy, encouraging patients to drink clear fluids all the way up until transfer to the operating room theater rather than stop fluid intake two hours prior to surgery, as recommended by both US and European guidelines.

Using a before-and-after study, the authors examined the impact of this policy change on rates of postoperative nausea and vomiting. They found that liberalization of fluid intake reduced postoperative nausea and vomiting without increasing the risk of pulmonary aspiration.

This article sparked considerable attention in both the medical and lay press. Today, Gregg Korbon, a SEE question writer, talks with Graham McCracken, one of the principal investigators of this study, to give us a little more depth into how the idea for this study came about, its findings, their reception by the
medical community, and their impact on future research and practice. Gregg, I’ll let you take it from here.

Gregg A. Korbon, MD: Thank you, Natalie. Hello, Graham. Tell us about yourself and how you got the idea for your study.

Graham McCracken, MB, BCh, BAO: I am a registrar in anesthetics and intensive care medicine currently based in Northern Ireland. I previously was based in Torbay Hospital as part of my specialty training. It was in that hospital where I was hoping to undertake a quality improvement project that I approached one of the consultants, Dr. Jane Montgomery, who is now the coauthor of our paper.

I inquired about any potential projects within the day surgery unit with which she was very active and she suggested that I undertake a small project initially that would compare our findings after a change in policy that Torbay Hospital had instituted in October 2014 whereby patients were allowed to drink clear fluids right up until sending to theater or transfer to theater.

That was October 2015; we had previously taken part in a national audit project in 2014, so we had a bit of data just to compare a small study against. So, I looked at the two weeks’ worth of data and referenced that against the previous national project we had taken part in. It was very small numbers initially and it showed that there was a decreased incidence of thirst postoperatively and it suggested there might have been a decreased incidence of postoperative nausea and vomiting.

So, that really prompted us to look at a much wider database that we have in Torbay Hospital. This is a routinely collected perioperative database with
many points relative to the patient pathway including timings of theater right through to patient satisfaction survey 24 hours postoperatively.

So, we looked at one year worth of data before the change and one year after and that’s really where we began with the study to see what change had taken place as a result of our change in policy.

Gregg A. Korbon, MD: What was your final study design and then also your finding?

Graham McCracken, MB, BCh, BAO: So, the study design itself was a retrospective analysis looking at this data pool. We tried to constrain our analysis to specific time points as best as possible prior to looking at it. So, we were stringent at looking at one year before the change versus one year after the change in an entire calendar year.

With this we knew that the policy change had taken place in October 2014 and we knew that it had been ratified at an anesthetic meeting – departmental meeting – in February 2015; so, therefore, we excluded a crossover period in our direct analysis.

So, we included patients from November 2013 to October 2014 and comparing that against patients from March 2015 until February 2016. In the findings we demonstrated a decreased incidence of postoperative nausea and vomiting; postoperative nausea decreased by about 25% overall and vomiting had decreased by about 20% relative rates. So, these were approximately 5% onto 3.5%; these were relative reductions. And this was demonstrated in total across 11,500 patients throughout that study time.

Also, we’d seen that patient satisfaction had also improved throughout that time period, patients rating their overall experience as very good. So, overall,
the findings were very positive from that retrospective analysis of our policy. It should be said that the policy itself, all patients were subject to this policy.

We looked at it as an intention to treat analysis and we didn’t measure the volume of fluids taken or which patients were compliant with it. We feel it has the strength that it very much is a real-world example and has good applicability elsewhere in that these things aren’t prescriptive for patients, these things don’t have to be monitored for patients, we just give patients the freedom to drink unrestricted clear fluids until transfer to theater. Patients were offered this in the waiting area. There was a sign encouraging patients to drink from a water dispenser.

So, very much the design was an analysis looking at our practice and demonstrating these improvements in patients’ experience and their overall morbidity.

Gregg A. Korbon, MD: Describe the actual time period from when they stopped drinking until they went through anesthetic induction. And also tell us about your procedure: how the patients would flow from your preop holding area all the way to surgery.

Graham McCracken, MB, BCh, BAO: Sure, OK. So, the patients would come into our day surgery unit, they would be in a general waiting area where there were water dispensers. From there they would be transferred to an anesthetic room where they would go through their WHO checklist, their World Health Organization checklists. And in that anesthetic room, induction of anesthesia would take place prior to transfer into the operating theater.
So, overall the practicalities of the time of sending for a patient, for transferring from the waiting area to theater, and the time between that and induction of anesthesia typically would have been at least 10 to 15 minutes.

We knew that this very much was in keeping with our understanding of gastric physiology, which some studies would cite that even a half-life of 15 minutes for gastric emptying is a conservative half-life. So, it could be roughly about 12 to 15 minutes is a half-life of the first order kinetics of emptying of clear fluids. So, you very much aligned the practicalities within theater with the understanding of gastric physiology.

Gregg A. Korbon, MD: What feedback have you had since you’ve published your study?

Graham McCracken, MB, BCh, BAO: Feedback on the whole has been, I would say, universally positive. I struggle to remember any negative feedback. It has ranged from those who have commended the hospital on their practice, there are those who feel that their hospitals should be doing that, there are those who feel that this is very much in keeping with the way fluid policy is progressing.

We have seen progression, for example, in the national pediatric guidelines, which now encourage clear fluids up to one hour prior to surgery. There are those who were seeking advice as to how to help institute such change in their departments.

So, overall the feedback has been overwhelmingly positive. It’s been very encouraging, indeed; and this includes those who are in high-ranking offices within anesthetic bodies who have commended us on this.
And certainly even it’s worth noting that the paper itself, which was published in the *European Journal of Anaesthesiology*, at the time of publication a commentary was written by two authors and, incidentally, those two authors were contributors to the European Society of Anaesthesiology preoperative fasting guidelines. These are the guidelines that all institutions would adhere to nationally typically within the UK, which is that clear fluids should be encouraged within two hours prior to surgery.

Their commentary that they did on our paper, was, again, very positive indeed and they very much made the case for the rarity of incidence of pulmonary aspiration of gastric contents. The huge numbers required were an RCT to be conducted in order to compare this and really highlighting that we had demonstrated safety and they questioned whether this could lead to worldwide change. So, that was very encouraging, indeed.

Gregg A. Korbon, MD: Very good. Now, you went on Twitter with your follow-up aspiration information. What happened after that?

Graham McCracken, MB, BCh, BAO: Yes. So, this was very much prompted by you, Gregg, when you got in contact with me on behalf of the ASA SEE Program. You asked did we have any more data at the time. Our study looked in total at the 11,500 patients. So, I went back in communication with the hospital. As I say, I rotate around as part of my registrar training. I believe in the US that’s the equivalent of residency. So, I made a contact with the team in Torbay Hospital just to see – follow up on our subsequent numbers of patients.

By that point we had upwards of 30,000 patients now who have gone through Torbay Hospital pathways under this policy of clear fluids. And I should say that the day surgery pathway, we used that because that was the pathway that had access to the perioperative data. All our patients were actually subject to
this policy, whether inpatient or day surgery. But that was where we had the
data pool.

But with regard to your question when you asked about follow-up of more
cases, we looked up all the cases we had through our Torbay Hospital because
at that point we would have data on safety and we knew that upwards of
30,000 patients now had gone through this pathway in Torbay Hospital and
since the change in policy, there were only two cases of aspiration of gastric
contents that required a higher level of care.

So, this was, again, very encouraging, demonstrating a very good safety
profile given that the underlying rate for aspiration in ASA I–II patients is
typically about 1 in 8,000 or 1 in 10,000 patients. So, in Torbay Hospital, it
equates to 1 in 15,000 currently in terms of an aspiration rate.

And I should say as well, both these patients, when we look closer at those
cases, they both had risk factors for aspiration: one was obese and another
likely had GERD, gastroesophageal reflux disease.

Gregg A. Korbon, MD: So, when you went on Twitter, I understand that you were approached
by a major journal for a follow-up study? Tell us about that.

Graham McCracken, MB, BCh, BAO: Yes, very much so. So, when I tweeted it via
Twitter—and this is one reason why I joined Twitter: I believe that social
media, there’s a power there to highlight a story was excellent. When I
tweeted that there, it got retweeted by some followers in London and really
went out and altogether it received several thousand retweets and likes. It
became the number one paper from the European Journal of Anaesthesiology
online.
And this then created further inquiries. We had an interview with the BBC Radio 4 Inside Health Program. This a national radio program whereby we got to highlight our change. We’ve been approached by other medical news outlets and conducted stories with them, highlighted our practice change.

And, as you mentioned, we’ve been approached by a very notable anesthetic journal who has requested that we follow this up and submit to them with a view to highlighting these 30,000 patients, which very much is our plan. This obviously is something that has just been highlighted by Twitter; it is a reality of what has happened in Torbay Hospital, but certainly having it documented in peer-reviewed research is the aim.

But suffice it to say at the moment, we are very content that this all demonstrates a very good safety profile and the practice continues at Torbay Hospital.

Gregg A. Korbon, MD: Tell us about your follow-up study. How do you establish safety when the base rate of aspiration is so low? Do we need to wait for a randomized controlled trial?

Graham McCracken, MB, BCh, BAO: Yes, it’s a very good question. A follow-up study will essentially be a further highlighting of our routinely collected data. There is no comparative group; I would submit that the comparator is all other institutions that currently undertake normal fasting programs. We know that the base rate, as mentioned previously, is 1 in 8,000 to 10,000.

If one wanted to undertake a noninferiority study, a randomized controlled trial in order to assess the safety of this, you’d need approximately 27 million patients if you wanted to demonstrate that with 90% power. If you said that
the baseline rate is 1 in 8,000, we will accept a change either side of that 10% relatively of the 1 in 8,000, you would need 27 million patients.

So, there are ways that we can try and estimate where we are. There’s what’s known as Hanley’s Rule of Three whereby if there are no instances of any adverse outcomes or any outcomes, what can we estimate the upper 95% confidence interval is of the true incidence. So, that’s known as Hanley’s Rule of Three because if there are no adverse events, we can say that then it’s at least 1 in 10,000.

We know that there were 2 adverse events in 30,000 and, as mentioned, those patients both had risk factors that may have necessitated tracheal intubation from the outset. With 2 cases of aspiration, the divisor is 6. So, we know that the 95% upper confidence interval is about 1 in 5,000 as an incidence of aspiration. Now, that’s very much saying it’s the upper confidence interval.

To describe the incidence of aspiration as a base rate is already 1 in 8,000 to 10,000. Again, that is an estimation itself. It will also have its own confidence intervals. So, suffice it to say at the moment, we have demonstrated an incidence of 1 in 15,000, but that is just highlighting where our 95% upper confidence interval would be.

It’s really highlighting, as well, that the feasibility of a randomized controlled trial in the context of such low numbers of adverse incidents of analyzing 27 million patients randomized to these protocols, all the best to a team that would undertake that. I think that is wholly impractical considering that a safety profile has been demonstrated that it is aligned with physiology and that we are seeing more evidence of this, even in the pediatric setting. We are seeing evidence of this in Scandinavia also.
It very much is becoming clearer that this is a safer practice and that postoperative nausea and vomiting and the patient satisfaction, of course, is excellent, but primarily we know that anesthesia is about safety and we are satisfied that we are demonstrating safety currently.

Gregg A. Korbon, MD: So, you’ve demonstrated improved patient satisfaction and comfort and right now it looks like you’re in the ballpark for proving noninferiority as far as safety. And I’ll be curious to see your follow-up article to see what numbers you end up with by the time you go to publication. But it sounds like you’re in the ballpark already.

With regard to those two patients that had aspiration, with risk stratification, let’s say you have a problem patient that presents: BMI of 47, symptomatic esophageal reflux, posted for surgery in the Trendelenburg position; do you still encourage unrestricted fluids and what do you recommend for patients at high risk for aspiration?

Graham McCracken, MB, BCh, BAO: As with most individual assessments, these are up to the anesthetist – the anesthesiologist – on the day in making that decision. As a hospital policy, typically this was the policy that governed all patients undergoing surgery.

In terms of individualizing it, I think the way I would frame this is what we are showing is that we can’t see that preoperative clear fluids up until sending for surgery increases the risk of aspiration, the baseline risk.

Clearly, these patients that you have described have an increased risk of aspiration and I would argue from the outset that these patients, as part of their anesthetic management, would necessitate tracheal intubation and some would
require a rapid sequence induction. So, these are things that would not be modified whether they were preoperatively fasted or not.

In terms of individually, if an anesthetist on the day wished to advise no further clear fluids from the point of assessment or from two hours before surgery, that, of course, would be their prerogative.

But as a policy, I am not aware that we had changed that policy individually for these types of patients as a general rule, and I would say that we’re showing that it doesn’t change the underlying aspiration rate and that the anesthetic management that you would institute for these patients anyway should still be carried out.

Gregg A. Korbon, MD: So, as a general policy, it’s at least as good as what you had before.

Graham McCracken, MB, BCh, BAO: Yes.

Gregg A. Korbon, MD: And there’s still room for individual risk stratification for your high-risk patients.

Graham McCracken, MB, BCh, BAO: Yes, I think that’s the key that we’re not showing that what we’re doing is increasing a baseline risk. We’re not changing that risk profile. These patients who have come in with their increased risk still have that increased risk, but we’re not increasing that risk further.

That is what I’m trying to highlight. I’m trying to highlight that all patients have their baseline risk and that what we are doing does not seem to modify that given the entire perioperative population that we have at Torbay Hospital: all range of ASA grid classifications, all range of BMIs, all range of
premorbid state. And we have 2 cases in upwards of 30,000 patients. That is what I would submit we are currently showing.

Gregg A. Korbon, MD: Right, and as I recall, those two patients did quite well and were discharged the next morning, as I recall.

Graham McCracken, MB, BCh, BAO: Quite right. Both patients – I can’t remember the temporal relationship to discharge, but certainly all patients recovered uneventfully very soon afterwards, yes.

Gregg A. Korbon, MD: Excellent. Well, as a seasoned general practice anesthesiologist, when you read these journals you hope upon hope that you’ll see something new and useful. And I would like to congratulate you for coming up with something that I think is actually useful and will have the chance of improving my practice.

Graham McCracken, MB, BCh, BAO: Thank you.

Gregg A. Korbon, MD: But, now for your bonus question for having done so well on the others, you are a patient scheduled for elective surgery at noon tomorrow and your preop instructions state nothing by mouth after midnight. So, what do you do as the patient knowing what you know?

Graham McCracken, MB, BCh, BAO: That’s a very good question. I would have to say that speaking from experience as a father with a son going through anesthesia, that I would follow the guidelines of that respective hospital. I don’t want to risk cancelation; I don’t want to try and prove a point on the day.

I feel it would be better for me were I to drink, very much so, and I think we are showing that. But what I have advised to those – particularly patients who
have contacted me via these outlets, one, I have tended not to engage as much in encouraging it for those who wish to flout their local guidelines.

But certainly if it were me as well I think I would follow local guidelines. I think these things are in place for their own local reasons and it may lead to cancelations and all sorts. So, I have followed it before as a father for my son and I think I would follow it for me as well.

Gregg A. Korbon, MD: I congratulate you…

Graham McCracken, MB, BCh, BAO: Thank you very much. And thank you very much for the encouragement that you give the study and I very much should say that I would commend the team at Torbay Hospital.

This was a decision that was undertaken just prior to my commencing in the department there in the year prior. They took a very bold step forward and I very much was able to reap the rewards of studying it and highlighting it.

And it’s been a great benefit to me in terms of starting a research career and also just to get to know those in the research community and to receive communication from – worldwide from Australia to America as we talk right now.

So, I should very much commend Torbay Hospital on what they have achieved and are achieving.

Gregg A. Korbon, MD: Yes. It sounds like you were in with a good group and that you continue to network to our advantage. Your interaction on social media has continued to improve your information. So, thank you very much for that.
Now, I appreciate your talking with us. Now, how can our listeners continue to follow your work?

Graham McCracken, MB, BCh, BAO: To follow the work specifically, I would say, number one, just in journals I’m hoping to highlight this in a notable journal and also read the paper itself. It’s on the *European Journal of Anaesthesiology*, type into Google and it should come up referencing postoperative nausea and vomiting. You can follow on Twitter. I will be highlighting any subsequent work we do on Twitter. And these would be ways to keep up with that.

Gregg A. Korbon, MD: What’s your Twitter account?

Graham McCracken, MB, BCh, BAO: It’s Graham McCracken. Someone had already taken Graham McCracken, so I joined the *M* at the end of Graham and the *M* at the beginning of McCracken together [@grahamccracken].

Gregg A. Korbon, MD: Very good. Well, thank you very much; really appreciate your time and look forward to seeing your follow-up article.

Graham McCracken, MB, BCh, BAO: Thank you very much, Gregg, and thanks for everything in helping us progress forward. It’s been a real pleasure.

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