Quality matters: A protocol-based strategy in ERCP training

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Abbreviations: ERCP, endoscopic retrograde cholangiopancreatography; SOD, sphincter of Oddi dysfunction; EMS, ERCP mechanical simulator

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In the recent years, there has been an increased effort to improve the quality of ERCP.^{1,2} There are a number of quality indicators for ERCP, two of which are cannulation of the duct of interest (intra-procedure) and complication rate (post-procedure).³ The medical literature has shed some light on these issues as they pertain to ERCP training. It has been noted that trainee involvement is associated with increase in ERCP-related complications along with other factors such as sphincter of Oddi dysfunction (SOD), history of post-ERCP pancreatitis, age <60 years and multiple pancreatic duct injections.⁴ Cannulation rate has been considered a surrogate of trainee competency. A number of studies addressed the level of competency of the fellows as it relates to the number of procedures performed. A landmark study was by Jowell et al.⁵ which suggested that the fellows achieved overall competency only after completing 180 to 200 ERCPs. More recently, Verma et al. followed a single endoscopist's learning curve for deep biliary cannulation and observed that the successful cannulation rate of >80% was achieved after 350-400 supervised procedures.⁶ In order to supplement the bedside teaching, simulators have been employed by some trainers. Following are the different types of simulators that have been introduced thus far: computer simulators, live animal models, porcine ex vivo models (Erlangen Endo-Trainer), modification of porcine ex vivo models (Neo-Papilla), and mechanical simulators.⁷⁻¹² To test the simulators' potential to enhance trainees' clinical competency, a multi-center trial was conducted which showed that the cannulation success rate was significantly higher for trainees who received EMS (ERCP mechanical simu-

lator) training versus those that only had traditional bedside teaching, in the early ERCP training period (69.6% vs. 47.1%, adjusted odds ratio=2.8, p=0.031).¹³

However, there have not been any studies that investigated the usage of specific protocols in trainee-involved clinical ERCPs, and the authors should be congratulated for conducting this very important study. Trainers have a tough job of balancing teaching and patient safety. Most trainers probably have their own intuitive or intentional policies as to when to provide verbal assistance only versus hands-on assistance versus scope take-over. But, having a specific protocol to follow would help standardize ERCP training between different trainers and centers.

In this particular study, Dr. Kwek and colleagues conducted a retrospective analysis on ERCPs performed by trainees and experts.¹⁴ Trainees' attempts at selective biliary cannulation were stopped and procedure taken over by the supervising expert endoscopist if the following factors were encountered: (1) failed cannulation after 5 attempts; (2) unsuccessful cannulation after 10 minutes; (3) edematous papilla; (4) pancreatic duct cannulation ≥ 2 times. The outcomes of ERCPs with trainee involvement were compared with those without trainee involvement. During the study period, the trainee group (TG) performed 85 procedures and the expert group (EG) 246 procedures. There was no statistical difference between the two groups with regards to mean procedural time, overall technical success rate (defined as 'successful completion of procedure, after selective ductal access'), and overall complication rate.

There are a few considerations worthy

of mention in terms of the study design, methods, and outcomes. As admitted by the authors in the discussion section, an ideal solution to answer the question regarding protocol-based ERCP training would have been a prospective study that compares one group of trainees (more than one person) that receive the protocol-based training versus another group of trainees with non-protocol based strategy, i.e. traditional method.

Because the study is based on the premise that uniformity is needed in training, definitions of terms within the particular protocol become crucial. As such, following items in the standard protocol should be clarified: (1) What does an “attempt” mean? Is it every time the cannulation device touches the papilla? (2) What is meant by the pancreatic duct cannulation? With wire or contrast or either?

TG having no significant difference from EG in procedural time and overall technical success despite having performed only 85 procedures, whereas the expert endoscopists had >1000 ERCP experience coming into the study, seems quite remarkable. This may mean that the trainee in this particular study was an extremely skilled endoscopist whose performance may not be easily reproduced by other trainees. The definition of technical success is not 100 % clear. If the cannulation process itself is not included in this definition, post-cannulation technical success may not be an ideal outcome measure since it has no direct relationship with protocol-based cannulation itself. If the cannulation process itself *is* included in this definition, it is hard to believe that the overall success is similar between TG and EG when the cannulation success rate for TG was only 57% (41 successful

common bile duct cannulation out of total of 72 cannulation attempts). Since post-cannulation aspect of the procedures were not protocol-based as far as the readers can tell, could it be that part of reason that TG had such a high success rate was due to expert assistance during this portion of the procedures?

Studies dealing with endoscopy training are not the easiest to conduct but are very much needed. Again, the authors should be commended for their efforts to improve ERCP training through standardization of teaching protocol. Although an optimal study, as mentioned above, would be a prospective trial comparing trainees receiving protocol-based training and those with non-protocol based training, another method may be to compare the procedure outcomes of current trainees who are going through protocol-based training with a similar cohort in the past who did not go through such training. Another potential future topic may be to study protocol-based teaching in aspects of ERCP that occur after the cannulation of the desired duct, i.e. sphincterotomy, stone removal, stent placement, etc. It would be interesting to see if the GI societies would adopt such protocol-based training officially, which would then move us one step closer to having standardized teaching between centers. Furthermore, having such a protocol may lead to production of “report cards” for trainees on which there would be collection of one’s performance on individual procedures that they can present to their interviewers during the job application process, as opposed to a simple form filled out by the mentor(s) including only the total number of procedures performed and overall subjective competency.

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