Aims: We are reporting single-institution's experience regarding the role of conservative management in 38 cases of minor and major anastomotic leaks [AL] occurring after primary surgery of esophageal atresia [EA] with tracheo-esophageal fistula [TEF] during last 17 years between 2000 and 2017. In this retrospective review, we are sharing our experience and protocol of management of AL with more emphasis to evaluate: (a) role of conservative treatment in major AL (b) role of extra-pleural approach in enhancing the success rate in conservative treatment in major AL (c) to define the criteria for major & minor leaks and (d) to evaluate the role of ventilation in primary EA surgery to control AL.

Methods: All these cases were operated through extra-pleural approach and out of total 203 cases, 38[18.7%] developed anastomotic leaks. In 29 of the 38 cases [14.3%], leak was minor and in 9 cases [4.4%] the leak was a major one. All these cases of leaks were managed conservatively.

Results: All cases of major and minor leaks showed spontaneous healing except one case of minor leak that died before healing due to major cardiac anomaly. For minor leaks, average healing time was 9.5 days while for major leaks it was 17.4 days. Overall mortality was 14.8% and there was no mortality directly attributable to major or minor leak. During follow up, the incidence of stricture was 40% in cases having anastomotic leaks, while in cases without a leak, the incidence of stricture was 23.3%. These all cases of stricture responded to regular dilatations.

Conclusion: We believe in cases of major AL, where primary repair is done by EP approach, a conservative treatment should be the treatment of choice. With this conservative approach of management of major AL, we not only save the native esophagus, the best conduit, but there is also less morbidity and mortality.

Keywords: Anastomotic leak, esophageal anastomotic leak, esophageal atresia, extrapleural approach, neonatal ventilation, tracheoesophageal fistula

INTRODUCTION

Today with the improvements in neonatal intensive care and anesthesia, morbidity and mortality due to associated pneumonia, prematurity, or sepsis are no more significant factors for esophageal atresia (EA) surgery. However, associated major anomalies and anastomotic leaks, especially the major ones, still remain the two important causes of morbidity and mortality in the immediate postoperative period.

Despite the improvement in overall care and survival rate, the incidence of anastomotic leak (AL) during the
Major anastomotic leaks in tracheoesophageal fistula repair

Since the line and on the contrary, others have preferred regarding the management of major AL, whereas few reports have some universal or practical criteria to differentiate a major leak from minor one, for example, some consider a leak as major if occurring within 2 days, whereas others consider it to be major up to 3 days or even up to 4 days. Another criteria described to ascertain major leak is, when there is deterioration in general condition of the baby, or an increase in the ventilator parameters. On the other hand, some have defined a major leak on the basis of extent of the anastomotic dehiscence or on the basis of amount of contrast leaks into the chest tube. Since the line of management varies in major AL, it is necessary to have some universal or practical criteria to differentiate the major and minor leaks, so that cases of minor leaks may not be inadvertently reoperated considering major leak. Regarding ventilation in EA surgery, many authors, in addition to associated diseases, also recommend an elective ventilation in cases of anastomotic tension to minimize the chances of leak, whereas few reports claim even better survival with routine postoperative ventilation in all cases.

**Materials and Methods**

A total of 231 cases of EA with tracheoesophageal fistula (TEF) were admitted in our Division of Pediatric Surgery at Sarkar Hospital for Women and Children, Agra, during the past 17 years (2000–2017). We collected and analyzed the data on baby’s gestation, weight, associated anomalies and other diseases, surgical procedure, ventilation records, complications and their management, and treatment outcomes.

**Preoperative workup**

The diagnosis of EA with TEF was confirmed by passing a firm catheter through mouth into esophagus plus a plain X-ray of the abdomen for gas in the abdomen. Besides, the tests required to confirm the diagnosis, our patients were also subjected to echocardiography. Echocardiography could be performed in 196 cases (85%) before the operation and in 22 cases during the postoperative period, whereas in 13 cases, it could not be done. We did not perform preoperative bronchoscopy or esophagoscopy for the upper pouch fistulae.

**Associated anomalies**

97 out of 231 cases (42%) had a total of 174 associated other anomalies. Congenital heart diseases (CHD) were the most common. 73 out of 218 cases had CHD (33.5%). Cardiac anomalies were divided into major and minor. A major cardiac anomaly (15 cases) was defined as either cyanotic CHD that requires a palliative or corrective surgery, or as one which clinically and hemodynamically presents as a cyanotic heart disease like persistent pulmonary hypertension of the newborn (PPHN) with bidirectional flow. Minor ones include patent ductus arteriosus, ventricular septal defect, and atrial septal defect occurring as an isolated defect or in combination (58 cases). Besides cardiac defects, there were gastrointestinal (10.8%), genitourinary (9.5%), spina bifida (3.9%), vertebral or skeletal (6.9%), and others (9.9%). Out of major cardiac defects, three cases were referred to higher centers for the management of EA where facilities for pediatric cardiology were available in addition to facilities for pediatric surgery. Two cases of associated major cardiac defects were operated at our center for primary EA surgery. In one such case, we missed the diagnosis during preoperative echo, and in another case, we could not do a preoperative echo, and it was diagnosed after discharge when the condition of the baby deteriorated.

Of 231 patients admitted as EA with TEF, 23 patients were either referred to the higher center or refused surgery due to associated multiple major or uncorrectable anomalies. However, patients were not rejected on the basis of weight, pneumonia, sepsis, or associated correctible anomalies. Thus, 208 cases were subjected to primary corrective surgery for EA. Of these 208 cases, 68% of cases weighed >2.5 kg, 23% between 2 and 2.5 kg, whereas 9% weighed <2 kg. Significant pneumonia or sepsis was present in 35% of cases. All were operated within 24–48 h of admission with intent to do a primary correction.
Operative details

All 208 cases were operated through the standard right extrapleural (EP) approach. If pleura was inadvertently opened, it was stitched at the end of the operation. However, if the tear was long, it was converted to transpleural approach (three cases). The anastomosis was done by interrupted sutures of 5–0 Vicryl in a single layer. In all cases, a transanastomotic tube was placed for postoperative feeding or gastric decompression in the immediate postoperative period. In all cases, a retropleural drain with underwater seal was used. In 47 cases, the gap was significant. In 42 of these cases, an anastomosis under moderate-to-severe tension could be accomplished. In three, anastomosis could be accomplished with the help of anterior full-thickness flap from the anterior wall of dilated upper esophageal pouch as described by Gough and Davenport and Bianchi. However, in two cases, the gap was too wide to do a primary anastomosis, and we opted for a staged correction by doing cervical esophagostomy and feeding gastrostomy in the same sitting. We did not make a preoperative or perioperative attempt to assess the gap between upper and lower ends, as they were operated with the intention of doing a primary anastomosis unless it was found impossible despite adequate mobilization.

Regarding mobilization of the esophagus, the upper pouch was fully mobilized in every case irrespective of gap, but the lower esophagus was not mobilized with an intention to gain length. We believe that excessive mobilization of the lower esophagus causes ischemia, which subsequently affects healing adversely, and there is a fair possibility of fibrosis leading to stricture even if anastomosis with mobilized ischemic lower end heals. Thus, we have to weigh whether to have an anastomosis under more tension with vascular lower end or with less tension but with ischemic lower end. In this regard, we followed the views of Spitz and preferred to have the anastomosis under little tension without mobilizing lower end, and this extra tension was taken care by ventilation. We believe that ventilation is better alternative to lower end mobilization. We also believe that dilated and hypertrophic upper pouch is more stretchable and gives more extra length as compared to similar extent of dissection of the lower end. In two cases, we come across the upper pouch fistula with trachea, and in both, it was closed. Five cases were excluded from the study, that is, cases that underwent a staged procedure (two cases) and cases where EP approach was converted to transpleural (three cases). Thus, 203 cases had a primary definitive repair by the EP approach.

Postoperative care

All cases received NICU care, intravenous fluids, antibiotics, and oxygen for the appropriate duration. Ventilation was an important part of the postoperative care. On the basis of ventilation, we have divided our cases into two phases. In Phase I from 2000 to 2008, besides specific indications of associated diseases (32 cases) such as respiratory (pneumonitis and HMD) or cardiac problems, we also used elective ventilation in cases where the repair was under tension (21 cases). In the rest of the cases during Phase I, babies were extubated either immediately or 2–4 h postoperatively. However, among the cases that were extubated successfully, 14 cases (15.5%) required ventilation due to deterioration within 48–72 h postoperatively. Therefore in Phase I, of 90 cases, 74.4% of our cases required postoperative ventilation for various reasons, 35.5% due to associated diseases, 23.3% due to anastomotic tension, and 15.5% due to deterioration postoperatively. Considering the fact that 15.5% cases required reintubation after successful extubation in the immediate postoperative period; in Phase II, that is, from 2008 onward, we adopted a policy to ventilate all cases postoperatively irrespective of associated diseases, tension, or Waterston’s status. Cases having anastomotic tension were ventilated for 5–7 days. Rest of the cases, with associated diseases, could be weaned from 3 to 8 days, with an average of 4.2 days. Those cases in Phase II that underwent routine ventilation, even where there was no obvious indication of ventilation as far as tension or associated diseases were concerned, were ventilated at least for 2 days with an average of 2.8 days. In 11 cases, preoperative ventilation was required due to associated moderate-to-severe diseases such as HMD, pneumonitis, and PPHN, and ventilation was also continued after the operation. Tube feeding was started on the 3rd or 4th postoperative day. The chest drain was removed after a check X-ray on 4th or 5th postoperative day. Contrast study was performed 8th or 9th day, and thereafter, oral feed was started if no leak was found. In cases where anastomosis was under tension, oral feed was started on the 10th or 11th day. However, for the past 10 years, we have been doing contrast studies only in some selected cases. Now, we mainly rely on some indirect evidences of satisfactory anastomotic healing such as a reduction of oropharyngeal secretions, aspiration of saliva from the stomach through transanastomotic tube, and no collection in an erect view of X-ray chest.

Postoperative complications

Anastomotic leak was the most important complication in the immediate postoperative period that was directly related to surgery. Of total 203 cases of primary repair,
leak occurred in 38 cases (18.7%). Of these, 18.7% cases of AL, major leak occurred in 4.4% (9 cases), whereas 14.3% (29 cases) had a minor leak. Criteria to differentiate major and minor leaks were the time of leak, that is, leaks occurring before 72 h were considered as major, whereas leaks after that period were considered as minor. In 27 cases, leak was diagnosed where the drain was intact, and in six cases, the leak was diagnosed on routine contrast study where drain had already been removed. In five cases, leak was diagnosed between the period of drain removal and before the contrast study, as leak was suspected due to fever and sepsis. All cases having major and minor leaks were managed conservatively, and the line of management was more or less the same in both. The conservative treatment consisted of the following: (a) an adequate drainage of saliva was ensured in all cases. In those cases where leak occurred before the removal of drain, the drain was left, and after 6–7 days, this underwater seal drain was replaced with a simple closed drain, because by that time, the parietal pleura usually starts adhering to the chest wall. In cases where the leak occurred after the removal of drain (5 cases), the EP space was easily entered extrapleurally through the drain site with the help of small artery forceps, (b) we started enteral feed through transanastomotic tube 3–4 days after the detection of leak. Starting with a small amount such as 5–10 ml, every 2 h, according to tolerance of the baby, we increased the feed up to 25–30 ml. By the term tolerance in relation to tube feeding in AL cases, we mean the amount of feed that causes minimum spillage of milk into the drain. In none of the cases, did we do a feeding gastrostomy or jejunostomy after the leak, and (c) antibiotics during healing period to prevent mediastinitis. Duration of healing: of 29 cases of minor leaks, in 28 cases, the leak stopped in 5–17 days (mean: 9.5 days). However, there was one death from minor leak group, on 6th postoperative day due to congestive cardiac failure before the leak could heal. Healing in major AL took 12–32 days (average: 17.4 days).

**Results**

There was no perioperative mortality. Overall, mortality was 14.8% within 6 weeks postoperatively. Causes of deaths were HMD or prematurity (five cases), cardiac failure (13 cases), pneumonitis or sepsis (nine cases), and others (three cases). Mortality in Phase I (2000–2008) was 17.8%, whereas, in Phase II (2008–2017), it was 12.4%. The possible reasons for better results in Phase II could be betterment in NICU care, better experience of operating surgeons, and policy for routine postoperative ventilation. There was no mortality directly attributable to major or minor leaks. However, there was one death from a minor leak group due to congestive cardiac failure before the leak could heal.

**Follow-up**

The patients were followed up for 12–18 months after their discharge from the hospital. In cases of dysphagia, we performed esophagoscopy and if required, a dilatation was performed. We did not do a routine esophagoscopy for the purpose of stricture or gastro esophageal reflux (GER). Of 173 survived cases, 151 could be followed up to 1 year. Of 151 cases, 41 (27%) developed an anastomotic stricture. These cases of stricture responded to regular dilatations and only 12 cases required >5 sittings and none required any surgical procedure. As far as, the incidence of stricture in cases of AL is concerned, of 37 such cases, 35 could be followed up to 1 year, and 14 (40%) developed esophageal stricture requiring dilatation. If we consider the incidence of stricture in terms of leak versus nonleak groups, we find that stricture was more common in the leak group (40% versus 23.3%). For GER, we were not able to do a proper study mainly, because we do not have the requisite setup. We refer cases of suspected GER to higher centers. In our part of country, parents do not come for follow-up on a regular basis, and many times come only when some problems or complications occur such as dysphagia, aspiration pneumonitis, or when some foreign body is suspected. Parents here take dysphagia due to stricture more seriously as compared to symptoms of GER.

**Discussion**

Although there are many factors that determine the mortality and morbidity in the immediate postoperative period in the primary EA surgery, associated major anomalies and major anastomotic leaks still remain the two very important factors determining the survival. The early complications are associated with surgical techniques as well as certain patient factors that, in turn, may compound the result of surgical technique. Even more challenging than the actual initial corrective surgery is the management of complications such as AL occurring in the early postoperative period. Despite improvements in overall care, the incidence of AL in EA, during the past five decades, is still very significant, and in recent reports of the past decade, it is around 16%–30%. In our series, the overall incidence of AL was 18.7%, and a major leak occurred in 4.4%. As far as management of minor AL is concerned, conservative management is the treatment of choice; however, management strategies for major AL are still not standardized. Since EA is a very common surgery and
leak is very common complication; therefore, guidelines for major leak have to be more precisely defined. Our discussion is mainly confined to some important aspects of major leaks such as how to define a major leak, appropriate management of major leak, and the role of ventilation in prevention and management of AL.

Criteria for major leaks

The criteria for major leaks are not clearly defined, and due to lack of that, the incidence of major leaks may vary in different series. Since opinion regarding the line of management in major AL varies in different reports, it is necessary to have some universal or practical criteria to differentiate the major and minor leaks. A review has revealed the following criteria for major leaks in different reports: (a) many authors have considered time of leak as the main criteria for differentiating a major leak from a minor one. However, there are differences of opinion regarding which postoperative day of leak detection should be used to differentiate major from minor leaks. For example, some have considered a leak as major if occurring before 48 h,[6,11‑13] whereas others considered a leak as major if occurred within 72 h[7,14] or even up to 4 days has been considered as a major leak;[5] (b) leaks were labeled major when, in addition to saliva in the drain, there were accompanying features of deterioration in the general condition, or increase in ventilator parameters;[8,12,15] (c) on the basis of extent of anastomotic dehiscence,[16,17] we feel it may not be easy to diagnose the size of anastomotic dehiscence with a contrast study alone, and we might require an MRI or thoracoscopy to examine disrupted anastomosis accurately. We did a try to scope esophagocutaneous fistulous tract in three cases of leaks, and in all three, the anastomosis was found to be only partially disrupted. With this very limited experience, we are not in a position to draw any inference. However, we believe that there is need for some more work on endoscopic study of leak cases to know the extent of anastomotic disruption (partial or complete) and also to know whether the size of leak is reducing with time or not, during follow-up on conservative treatment; (d) Bawa et al., in addition to clinical deterioration, also considered amount of saliva in drain as an important criteria for major leak.[12] A major leak was defined if ≥20% of the total gastrostomy tube feed is coming out into intercostal drain; and (e) Gupta et al.[18] considered it to be a major leak if in a contrast study, most of the contrast entered the chest cavity with clinical evidence of mediastinitis and sepsis.

Author’s view

We feel that, of all the criteria mentioned above, time of leak and deterioration in clinical condition are the two most important factors for defining major AL. Besides these, we feel that there are two other important factors that should also be considered while defining a major leak or deciding line of management for major leaks, namely, (a) importance of operative approach (EP vs. TP): although the incidence of AL is more or less same in both approaches; however, once a leak occurs, especially in major leak, there is a significant difference in clinical course, morbidity, mortality, ventilation, hospital stay, and need for surgical intervention in both approaches. Therefore, the importance of EP cannot be underestimated in major leaks, as the further course of disease after leak would be much better in EP, and (b) gap or tension on anastomosis: if a leak occurs in a case where the anastomosis is performed under tension, it is likely that the gap may increase due to friability and tension on the suture line. In such leaks, a redoanastomosis does not seems to be a good option, as it is less likely that edematous and friable ends will hold the re-suturing, that too at the operative risk of rethoracotomy. In our report, out of nine major leaks in three cases, leak occurred where anastomosis was under tension, and in all these three cases, healing occurred by the conservative treatment.

Options available after major leak

Conservative management

We have managed nine cases of major leaks and 28 cases of minor leaks by the conservative approach. We believe, in major leaks occurring after the EP approach, conservative approach should be the treatment of choice. The possible advantages of EP over TP approach in case of a major leak are as follows: (a) the pleura play a significant role in healing of major leaks. Although pleura looks a delicate and thin membrane, it is a strong mechanical and biological barrier keeping all contaminated saliva extrapleurally; (b) there are evidence that contact or cover of pleura over the leak site increases the chances of healing.[18,27,28] These reports claim that pleura is a mesothelial layer like peritoneum, and the beneficial effect of pleural flap is believed to act in the same way as an omental patch following bowel anastomosis; (c) there is no significant mechanical pressure on the lung or on its functional capacity in EP, whereas in TP, many times major leaks significantly affect the lung function and requires ventilation.[18,29] In our report, none of the major leak cases required extraventilation due to a leak; (d) enteral feed can be started early in major AL patients operated by EP; and (e) mortality in major leaks after TP is significantly high.[12,30] One such series has reported a 40% mortality with conservative management among cases of major AL occurring in TP approach.[12]
Surgical intervention after major AL

There are two common surgical procedures that have been recommended after major AL. One is resuturing of disrupted esophageal ends and the second is a palliative procedure where we do a cervical esophagostomy plus a feeding gastrostomy. Although we have operated our cases by EP, we have reviewed the literature regarding surgical intervention in major AL occurring in both EP as well as TP approaches with the aim of finding answers for the following: (1) how should one decide between conservative and surgical intervention in major AL? and if surgery is indicated for major AL, what should be the guidelines in choosing one of the two procedures: redo versus palliative; (2) do we need to attempt conservative treatment in all cases of major AL before going in for a redo or palliative surgery?; and (3) does the approach of primary repair (EP or TP) affect the decision for surgical intervention in major AL?

Resuturing versus palliative procedure

A second attempt to suture partially disrupted esophagus in major leak immediately, or whenever it is detected, as an attempt to save native esophagus has been recommended by many authors. They have recommended a reexploration in all major leaks to see whether it is partial or complete disruption. In case of a partial disruption, they recommended resuturing while in case of complete or irreparable disruption, a cervical esophagostomy plus suture ligation of the distal esophagus and gastrostomy should be done. While doing a redo surgery, some have recommended an additional reinforcement of resutured esophagus: (a) with pleural cover, (b) with pleural patch and intercostal muscle flap, and (c) the use of pericardial flap. On the contrary, a few reports have preferred a cervical esophagostomy over redo surgery. There are many other reports where authors have used both redo and palliative surgery in major AL.

Regarding the role of approach (EP vs. TP), in majority of reports where an early surgical intervention has been recommended in major AL, have been operated by TP. This shows that in TP, due to deterioration in general condition, the baby cannot tolerate the conservative treatment well for a long time, and therefore, an early intervention has to be considered. Those who tried a prolonged conservative treatment in TP had high mortality. While deciding for surgery, we should also consider the following facts: (a) even a resuturing is no guarantee against a leak, and it can frequently reoccur; (b) if resuturing fails, would it be possible for these sick babies to tolerate a third surgery for palliation? this palliative surgery itself is a major operation and involves at least two procedures (cervical esophagostomy plus gastrostomy), with or without thoracotomy for ligation of lower end of the esophagus, if it is not to be done transtially during gastrostomy; (c) interestingly, there is an evidence that conservative treatment is successful even in cases where resuturing has failed, and these reports probably indicate that surgical intervention in major AL can be avoided if we wait for some more time; and (d) we have successfully managed major AL even in cases of tension on anastomosis. We believe that instead of going for surgical intervention, an adequate trial of conservative treatment in EP is justified and if at all surgical intervention is decided on, one should consider all the important issues discussed above.

Role of ventilation in prevention of leaks

Besides, associated problems such as pneumonitis or prematurity, ventilation has also been used by many authors electively in cases of Anastomotic tension to prevent AL. There are many pediatric surgery units which recommend a routine or elective ventilation in all operated cases. Since AL can occur despite a favorable anatomy and meticulous surgical technique, we also need to work on factors responsible for leaks in favorable anatomy. Like Spitz, we also believe that a routine or prophylactic ventilation can reduce the incidence of leak. Although in our cases, the incidence of leak was less in Phase II where we electively ventilated all cases as compared to selectively ventilated group of Phase I (15.9% vs. 22.2%); however, we believe that there are some other factors such as betterment in NICU care and anesthesia or better experience of operating surgeons that have also contributed to this reduced incidence of leak in electively ventilated cases. Since it is a retrospective study of long duration over 17 years where selective and elective ventilations have been used in different periods, we feel some prospective studies with a protocol of selective and elective ventilations in similar conditions may be required to establish the role of elective ventilation in prevention of leaks more precisely. Routine ventilation probably helps by (a) in keeping neck stable in flexed position; (b) frequent oropharyngeal suctioning is not required, thereby minimizing possibility of damage to anastomosis; (c) helps in adequate oxygenation for tissue healing, as esophageal ends may suffer ischemia during mobilization or hypoperfusion due to congestive heart failure or septic shock; and (d) in postoperative period, sometimes, there may be a sudden deterioration and for resuscitation, we need to intubate the baby with neck flexed or with minimum extension of the neck. A single wrong attempt of intubation, with slipped tube into esophagus can damage or disrupt the anastomosis. Such problems occur mostly within 2–3 days after...
operation, and therefore, we believe, to avoid such iatrogenic damage, it is better to continue ventilation for 2–3 days, in those cases also which otherwise do not have significant risk factors or anastomotic tension.

**CONCLUSION**

In case of an EP approach of the EA repair, chances of healing of anastomotic leaks with conservative treatment are very high for major leaks, and almost all major leaks, including the cases having anastomotic tension are expected to heal. With this conservative management of major AL, we are able to save the native esophagus with less morbidity, mortality, and cost of treatment in terms of NICU stay and ventilation. If the EP approach is used, there is no need to define AL as major or minor. We believe that in cases of major AL, where primary repair is done by EP approach, a conservative treatment should be the treatment of choice.

**Acknowledgment**

We gratefully acknowledge the contribution of nursing staff of our NICU for better survival of our patients of esophageal atresia. We are also grateful to Ms Neelam Mehrotra for her help in drafting this manuscript.

**Financial support and sponsorship**

Nil.

**Conflicts of interest**

There are no conflicts of interest.

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