Review

The current role of hybrid procedures in the stage 1 palliation of patients with hypoplastic left heart syndrome

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Summary

Hypoplastic left heart syndrome is a relatively common cardiac malformation, accounting for 4–9% of children born with congenital heart disease. Since 1981 the mainstay of treatment has been the Norwood series of operations which have been variously modified, most recently using an RV–PA conduit (Sano shunt). With these surgical modifications and with increased experience in perioperative care survival for the surgical approach to completion of stage 2 palliation has improved to 70–80%. However, in 1997 when surgical results were poorer, interventional cardiologists explored the possibility of hybrid palliation of these children using a combined transluminal and closed surgical technique as it was perceived this would be less traumatic. Poor initial results caused many to discontinue this approach but some persevered, and with increasing experience survival to completion of stage 2 following hybrid palliation is now 50–80%. Although these results may superficially appear to be poorer than for surgery, it must be observed that increasingly the hybrid approach has been used by many groups as palliation for the highest risk cases (particularly small size and adverse cardiac factors). This review therefore considers what is the optimal management of children with hypoplastic left heart syndrome currently, and, specifically, what is the role for the hybrid approach in palliation of patients with hypoplastic left heart syndrome?

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1. Introduction

Originally reported in 1993 [1], hybrid procedures for initial palliation of hypoplastic left heart syndrome (HLHS) were devised as an alternative to the stage 1 Norwood procedure as the risk of surgical palliation was so high [2,3]. However, early enthusiasm rapidly became tempered by poor medium-term results [4] and as experience with the surgical approach increased and results improved, hybrid procedures became less popular. Yet over the last 6 years there has been renewed interest in this interventional approach with numerous reported series. It is therefore pertinent at this time to consider whether this is just reinventing the wheel, or does the hybrid interventional approach now have a role to play in the management of patients with HLHS?

At the outset of this discussion it is important to understand that the two approaches cannot be compared solely by outcome. This is primarily due to the fact that in no report are patient populations comparable; hybrid groups tend to be weighted towards smaller patients and those with other significant risk factors. In addition, as well as being a first stage in a surgical series, hybrid palliation can be used as a bridge to transplantation, a strategy which is used for three reasons; unit preference, for natively poor risk cases, or as a 'bail out' if the child deteriorates following initial palliation.

In many reports it is difficult to ascertain the reason for transplantation and valid comparison of original strategies is therefore not possible. These cases will, however, still be considered in this review to determine the overall role of the hybrid procedure in the management of patients with HLHS. Finally, it is also important to note that a stage 2 hybrid procedure incorporates both stages 1 and 2 of the surgical sequence and it is only after this point that the palliation pathways come together. Outcomes for the various strategies can therefore only be compared following completion of stage 2.

2. Approaches to palliation

The pathophysiology of these patients is that there is effectively only one ventricle capable of sustaining a cardiac output (Fig. 1), and this ventricle ejects into the pulmonary circuit. Systemic perfusion is, therefore,
dependent on antegrade flow across a patent arterial duct and the pulmonary vascular bed is unprotected. Successful completion of third stage palliation of single ventricle abnormalities requires that pulmonary vascular resistance is very low to permit passive return of systemic venous blood; prolonged exposure of the pulmonary vascular bed to a high pressure, high flow circulation must therefore be avoided.

2.1. Surgical approach

In surgical palliation, essentially the arterial duct is replaced by a direct anastomosis between the pulmonary artery and aorta either directly or combined with homograft augmentation of the aortic arch (Fig. 2). Pulmonary blood flow is then provided, classically by a modified Blalock-Taussig shunt (Fig. 2a), or more recently a right ventricle-pulmonary artery (Sano) conduit (Fig. 2b).

Following a progressive series of attempts to palliate children with HLHS, Norwood first described what is now considered to be the “classic” Norwood 1 procedure in 1981 [5]. As for all new procedures there was a learning experience, and in the first group of nine patients there were five early and one late death. With increasing experience results improved rapidly, and in a subsequent report in 1988, in a series of 104 patients there were only 30 early and 11 late deaths giving an operative mortality of 29% and medium-term survival of 60% [6]. Since this time there have been a number of minor modifications including techniques to prevent the requirement for exogenous materials in the arch reconstruction [7]. However, the most significant of these modifications was championed by Sano who reintroduced the right ventricular/pulmonary artery conduit but used much smaller conduits than the ones initially employed by Norwood [8].

Most deaths following the standard Norwood stage 1 procedure occur during the first 48 h postoperatively due to haemodynamic instability caused by rapid fluctuations in pulmonary vascular resistance. The general approach traditionally adopted has been to control pulmonary blood flow by ventilation, inspired gases (particularly nitrogen) and systemic vasodilators. Sano hypothesised that using a right ventricle to pulmonary artery conduit would reduce this instability by preventing diastolic run-off. In his initial report of 19 patients it was reported that ‘...haemodynamic instability never occurred...’ despite no specific manipulations to control pulmonary blood flow, and diastolic pressures remained above 40 mmHg at all times [9]. This was not a select group of patients; aortic diameter was 3.3 mm (range 1.6—7.6 mm), patient weight was 2.8 kg (1.6—3.9 kg), and moderate or severe tricuspid regurgitation was present in 37%. In this group of patients hospital survival was 89% at a time when the national mortality in Japan for the classical Norwood was 60% [10]. There were two late deaths due to shunt occlusion and a further two patients died following the Glenn shunt giving a survival rate of 68% to completion of stage 2.

While this report includes the learning curve with this procedure, a later report of 73 patients operated upon in a number of centres across the country demonstrated a 71% 1-year and 68% 2-year survival for established practice in a similar group of patients in whom the intention was to perform the Glenn during the first year of life (mean 6.9 months, range 2.6—14.6 months) [11]. Similar improved results using the same surgical modification were found by Pizarro and Norwood, who reported a stage 1 operative mortality of 6% with 86% survival to stage 2 completion [12].

Over time, there have been considerable improvements in the management of patients undergoing Norwood stage 1 surgery both in surgical techniques and perioperative care. Tweddell et al. reported their experience using the classical Norwood operation over a 9-year period and found that with the progressive application of new strategies early survival for the classic stage 1 Norwood improved from 53% pre-1996 to 93% post-1996 with survival to stage 2 completion similarly improving from 44% to 81% [13]. These new strategies were continuous SVC oxygen saturation monitoring, post-bypass modified ultrafiltration, phenoxylbenzamine administration, the use of aprotinin, modification in surgical technique to excise the aortic isthmus entirely, and continuous cerebral perfusion (30—40 ml/kg/min). By univariate analysis, all of these strategies were associated with improved survival both early and to completion of stage 2 palliation.

Progressive improvements with operative era have also been reported by other centres. In Toronto early mortality has fallen from 59% (1990–1993) to 19% (1998–2000) and survival to completion of stage 2 has improved from 31% to 68% for the same time periods [14]. Similar to the Wisconsin experience, this improvement was associated with changes in surgical techniques (not including the Sano), avoidance of circulatory arrest, and aggressive manipulations to balance the parallel circuits. Likewise, in Melbourne a significant improvement in survival was found between time periods with early survival improving from 33% (1983—1995) through 50% (1996—2002) to 76% (2003—2004), and survival to stage 2 completion of 24% and 48% for the first two time periods [15].

Fig. 1. In patients with classical hypoplastic left heart syndrome all left-sided cardiac structures are small and the left ventricle is inadequate to provide a systemic output.

Interestingly, one of the techniques Norwood abandoned used an aortic arch/pulmonary root reconstruction as used in the classic stage 1 Norwood but was completed using a right ventricular to pulmonary artery conduit as is now advocated in the Sano modification [5].
This was attributed to active measures to manipulate circuit balance in the second epoch (high haemoglobin, hypoxia, hypercarbia, and systemic vasodilatation) and the adoption of the Sano shunt in the final time period. Therefore surgical survival to stage 2 completion is now consistently between 70% and 80% across a number of units. This is therefore the standard by which any change in the management of patients with HLHS must be judged.

It has however been shown that there are subgroups of patients within the spectrum of HLHS which have poorer outcomes when treated by traditional surgical palliation. Analysis of early experience suggested that multiple variables contributed to poor outcome, specifically low birth weight, prematurity, small ascending aorta, severe tricuspid regurgitation, poor RV function, obstructed pulmonary venous return (TAPVC or restrictive interatrial communication) and longer duration of deep hypothermic circulatory arrest \[13,16\]. Increasing experience has reduced the impact of most of these, yet analysis of results from many centres even nowadays still shows birth weight less than 2.5 kg to be an independent risk factor for poor outcome with an odds ratio of between 2 and 7 \[13,14,17—19\]. It has been argued that the use of the Sano modification provides more haemodynamic stability particularly in small babies, but for many groups lower birth weight remains an independent risk factor even in this group \[17\].

In summary, over 27 years of significant improvements in outcome following surgical stage 1 palliation for HLHS have been achieved with early survival reaching up to 93%. Yet despite this, subgroups remain for which the surgical risk remains high. Moreover, despite these significant improvements in early results, little improvement has been achieved in interstage survival with 12—15% of patients still dying between stages 1 and 2 \[13,14\], a figure which is not that different from Norwood’s earliest results \[6\].

2.2. Hybrid approach

Compared to almost 30 years of experience with the Norwood stage 1 operation the hybrid approach is relatively new. Stenting of the arterial duct was first reported by Gibbs et al. in 1992 \[20\] to maintain ductal patency in the setting of the pulmonary atresia with intact ventricular septum, and by Ruiz et al. \[21\] to maintain patency of the arterial duct in the setting of HLHS in patients awaiting a suitable donor for transplantation to prevent the complications of long-term prostaglandin infusion. Both groups reported short-term success with histological confirmation of stent endothelialisation and absence of clots. Following on from this experience, Gibbs et al. \[1\] pursued a hybrid approach to complete palliation of patients with HLHS in which the defect in the atrial septum was enlarged surgically or by balloon septostomy, the branch pulmonary arteries were banded surgically through a median sternotomy, and the duct was stented percutaneously. However, initial results were poor. Of four patients so treated, two died in hospital within 2 weeks of the intervention due to right ventricular failure and excessive pulmonary blood flow, one was still in hospital 5 weeks following the intervention due to cardiac failure, and only one was discharged after 2 weeks. Further, blood flow was frequently lost to the right upper lobe due to obstruction from the PA band.

Medium-term results offered no more hope. Animal experiments \[22\] and clinical experience \[4\] suggested that ductal patency could reliably be maintained, and although there was some evidence of intimal ingrowth and resultant stenosis particularly if the stent did not reach the aortic lumen, this was not limiting and could be adequately relieved by redilatation with or without further stent placement. Thrombosis also did not occur. However, clinically this experimental success was not translatable into clinical practice; of eight patients with HLHS palliated by a hybrid approach, all were dead within 30 months of the procedure \[3\]. The primary problem appeared to be controlling pulmonary blood flow with 50% dying within 10 weeks due to right ventricular failure secondary to excessive pulmonary blood flow. Further two patients died during cardiac transplantation, and although the details are not recorded this may have been due to elevated pulmonary vascular resistance following prolonged exposure of the pulmonary...
vasculature to excessive blood flow. A further child died during aortic arch reconstruction 12 days following the hybrid procedure, and the final child died 30 months following palliation due to right ventricular failure which occurred despite apparently adequate pulmonary artery banding. These results led the writers to conclude that ‘...with HLH(S), the duct may be kept open, but quality of palliation is poor because of difficulty in controlling pulmonary blood flow even after banding of the pulmonary arteries: the most recent results of the Norwood operation and its modifications are clearly superior.’

Despite these dismal results, others persisted with the techniques and in 2002 Akintuerk et al. described their experience with 11 patients [2]. The approach adopted by this group involved initial stenting of the arterial duct, which was technically successful in all cases, followed 1–3 days later by surgical pulmonary artery banding. The tightness of the band was modulated to achieve distal pulmonary artery pressures which were below 50% systemic, a reduction in oxygen saturation to 80 ± 5%, and a 4 m/s gradient across the band as measured by continuous wave Doppler. All patients survived this combined first stage though one child died before stage 2 from right heart failure caused by recoarctation of the arterial duct where it had not been covered by the original stent. The stage 2 procedure was performed between 3 and 6 months later; in two patients this was heart transplantation and in the other eight a modified Norwood procedure. In the stage 2 procedure is much more invasive than a classic stage 2 Norwood and essentially combines both Norwood stage 1 and 2. In it, all stent material is removed, the aortic arch is reconstructed, and a bidirectional cavopulmonary shunt is performed. In this report, of all patients undergoing modified stage 2 palliation there was one death with an overall survival rate of 82%.

These results could be considered the learning curve in this group’s experience and it might be expected that results improved with further experience, but in a later report of 58 patients, results were essentially identical [23]. In this later report the technical approach had developed so that surgical banding of the pulmonary arteries was performed first by ducal stenting later as an elective procedure. It is of note that in this series the average patient weight was only 2.7 kg (1.3–4.1 kg). Second stage management was by transplantation, combined Norwood 1 and 2, or biventricular repair depending on anatomic and functional criteria. Overall actuarial survival for all patients undergoing the hybrid stage 1 procedure was 83%, and a further two died after the stage 2 surgery which gives a combined survival to stage 2 completion of 79%.

Others have adopted a slightly different approach with bilateral banding of the pulmonary arteries and maintenance of ductal patency being achieved by either prolonged infusion of PGE1 or a main pulmonary artery to descending aortic shunt [3]. Using this approach four patients were kept in ICU between 3 and 4 months awaiting 2nd stage repair. However, all patients survived and progressed to the Fontan stage.

Despite these encouraging results, not all groups have fared so well. In a series of 29 patients reported in 2005, 10 were considered part of the ‘learning curve’ while the following 19 were considered separately as ‘established experience’ [24]. The approach adopted by this team was to band the pulmonary arteries initially, either as a separate operation or as the first part of a combined procedure. In the first two patients, a novel intraluminal pulmonary artery flow restrictor was used to control pulmonary blood flow, but this was abandoned in favour of open surgical banding due to technical problems with its deployment. In the initial 10 patients 3 died around the time of the 1st stage, 3 died between stages, and a further 2 died at the time of the second stage operation; there was one final late death. The three early deaths were procedure related, two from problems while deploying the transcatheter flow restrictor and one from intractable arrhythmias following atrial septostomy. The two interstage deaths were also technical issues, one pulmonary vein avulsion during balloon atrial septostomy and one recoarctation. Both deaths following stage 2 surgery were from myocardial failure caused by lung standing coarctation when surgery was undertaken for salvage. In the later experience, of 19 patients embarking on this route there was again an overall survival of 79%. One patient died after stent placement due to complications of stenosis of the distal transverse arch, while two died following stage 2 palliation.

Similar first stage results have been reported by other groups [25]. Although the second stage in this series was transplantation, Boudek et al. reported an overall 6-month survival of 76% in a group of 40 patients undergoing stage 1 hybrid palliation using a different intraluminal pulmonary flow limiter. Of the deaths, two were considered technically related, one occurring following balloon atrial septostomy, while the other patient developed a preductal coarctation 3 months after stent placement.

The initial argument for the development of a hybrid approach to the management of patients with HLHS was that the risk with conventional surgical methods was prohibitively high. With specific subgroups suggested as being of particularly high risk (low birth weight, premature, small ascending aorta, poor RV function, significant tricuspid regurgitation) it is therefore of particular interest to consider if the hybrid approach offers better survival than surgery in these patients. Bacha et al. studied 14 neonates weighing 2.2–3.3 kg, all of whom had significant major risk factors [26]. First stage hospital survival was 78.5%, two of the three deaths being directly related to the procedure. Two more patients died between stages, and a further two patients died during the second stage operation giving an overall mortality of 50% (one patient was awaiting second stage surgery). Even accepting the ‘high risk’ population which made up this series the results do not appear to offer benefit over surgery especially as many of the risk factors cited are no longer considered significant by many surgeons. The authors concluded that hybrid stage 1 palliation is a valid option in high risk neonates though their further contention that ‘...as experience is accrued it may become the preferred alternative’ is harder to support from these results.

What is clear, however, when managing these high risk patients is that no single approach is appropriate for every centre; it is important for each institution to compare its mortality for these different approaches before deciding which to adopt. In a report from Brazil of a relatively recent...
experience (2004–2006), although mean body weight was only 2.9 kg and 50% had mild–moderate RV dysfunction at presentation, mortality following the hybrid stage 1 was 60% (9/15) and further 3 (of 4) patients died after the combined stage 2 procedure [27]. In contrast, in a population weighing 1.6–3.7 kg reported from Giessen, overall survival, including the stage 2 procedure was 75%, at a time when mortality for the classic surgical stage 1 Norwood in the same institution was 40% [28]. Finally, patients allocated over the same time period to either conventional stage 1 Norwood or the hybrid procedure (by an interdisciplinary conference on a case-by-case basis) in Toronto showed no difference in mortality between the two approaches (71.4% and 68%, respectively) [29]. (It should however be noted that this hybrid experience includes the initial learning curve of the institution in comparison to results from a well established Norwood programme.)

As latterly many groups have demonstrated increased stability in the hybrid patients compared to the surgical Norwood 1 patients following the procedure, manifest as reduced ventilation times and shortened ICU and hospital stays, Li et al. sought to ascertain whether this was attributable to improved haemodynamic and oxygen delivery parameters after the hybrid [30]. It was found that there was no significant difference in heart rate or blood pressure between the groups though the diastolic pressure in the hybrid group rose faster than the surgical group following the procedure. However, immediately post-procedure the SVR was found to be higher in the hybrid group with a significantly lower systemic blood flow, cardiac output, and stroke volume though these parameters recovered to normal values faster in this group than in the surgical group. Pulmonary blood flow was initially similar between the groups post-procedure resulting in a higher Qp:Qs ratio in the hybrids (0.4–5.7 vs 0.3–3.3), and this resulted in higher PaO2 and oxygen saturations. Finally, oxygen delivery and oxygen consumption were lower in the hybrid group though they also recovered to normal more rapidly than in the surgical group.

It should also be observed that pulmonary artery banding itself is not a benign procedure and causes significant myocardial injury. Immediately following banding there is myocardial inflammation and myofibril damage associated with increased expression of cellular adhesion molecules [31]. This is associated with evidence of apoptosis within 24 h [32]. Down-regulation of calcium-binding proteins also occurs [33] and there is decreased mRNA encoding for proteins associated with calcium release [34] both of which directly have a detrimental effect on myocardial contractility.

3. Longer term considerations

The evidence considered so far is reasonably comparable for surgical and hybrid approaches and allows fair comparison between them, yet the early decisions concerning the palliative approach adopted impact on the child’s life long development. Although long-term results for morbidity and mortality are available for the traditional surgical approach comparable data are as yet not available for the hybrid. Comparison of results for late follow-up cannot therefore be made, but it is relevant to consider what information is currently available not only to glean as much information as we can at present, but, more importantly, to be aware of what research needs to be undertaken in the future to ensure that a valid conclusion can be drawn. Further, although so far the focus has concentrated on mortality data, long-term morbidity, particularly neurodevelopmental, is of extreme importance.

In patients who survived the stage 2 procedure after initial surgical palliation, interstage survival between stages 2 and 3 is 93–100% [35–37] and stage 3 mortality 0–4.4% [38,39]. Following this there is an early attrition rate of 1–1.5% per year [38,40] followed by a plateau with actuarial survival at 5 and 10 years (in an historic group of patients) of 50% [41].

Children with congenital heart disease are at high risk for cognitive, motor, and other neurological deficits. In standard IQ tests, patients with HLHS who have undergone traditional surgical palliation have significantly lower scores (86.7) than normal children, though not significantly different to other children with palliated single ventricle lesions (89.1) [42]. However, CT and MRI brain scans show that of children who have undergone the surgical Norwood sequence, 62.5% demonstrate ischaemic changes, infarcts, or cerebral atrophy compared to 16.5% of patients with other forms of single ventricle anatomy. While some patients demonstrate congenital cerebral abnormalities, following the Norwood procedure new or worsened cerebral changes are found despite the adoption of regional low-flow techniques in 73% of patients compared to 23% showing ischaemic changes preoperatively [43]. It has been suggested by Hoffman et al. that patients with more abnormal neurodevelopmental outcomes had significantly lower systemic venous saturations postoperatively than those with higher scores and that the risk of neurological abnormality correlated with the duration of the mixed venous saturation being below 40% [44]. While this has led this group to continuously monitor MVO2 and aggressively intervene when they are low, interventional strategies which avoid the primary cause (poor cardiac output) may result in better neurodevelopmental outcome. Others have shown deep hypothermic circulatory arrest to be an independent risk factor for poor neurodevelopmental outcome, and therefore any technique which avoids these two insults may be beneficial. Such a technique may be the hybrid approach, but supportive data are, as yet, unavailable.

Being a new technique, robust comparative data are not available for the hybrid approach as reported survivors following stage 2 hybrid palliation number only 71. In these series the mortality between stages 2 and 3 has been 3–7% [24,45] and no mortality has been reported during the stage 3 procedure though these number only 16 in total. These mortality results compare very favourably with those for surgical palliation though little has been reported regarding long-term survival. Further, little has been reported concerning morbidity (particularly neurological). It could be anticipated that this would be less than following the traditional surgical approach as the use of bypass in high risk neonates is avoided but there are no data currently available to support this contention. Future research into this is essential to prove the superiority of one of these two palliative strategies.
4. Conclusions

In light of the above experience with various approaches to the palliation of children with HLHS what can be concluded of the current role of hybrid procedures? It must be emphasised again that published results of the two techniques cannot be directly compared as in no report are the two groups identical; a randomised study has yet to be performed. Even in those studies comparing results in a single institution, patients have not apparently been equally allocated between the two groups. Indeed, patients palliated by hybrid techniques are often a higher risk group and surgeons should be aware of this bias when defending their position; mortality may have been transferred. In addition, with analyses currently available, many of the ‘hybrid’ papers are biased from a learning curve and this must be considered when comparison with a procedure of 30 years standing is made. However, as evidenced above, the hybrid procedure is far from benign with clinically important myocardial injury occurring following pulmonary artery banding and problems with balancing parallel circuits with the significant potential for pulmonary overcirculation and pulmonary vascular damage.

There are undoubtedly situations when it is desirable to avoid bypass such as in children with preoperative multigland failure secondary to systemic hypoperfusion due to pulmonary over-circulation (particularly necrotising enterocolitis), or intracranial bleeds. Previously, short-term bilateral pulmonary artery banding has been shown to achieve adequate balance between the pulmonary and systemic circuits to allow rapid recovery of end-organ function so that a successful surgical stage 1 Norwood procedure was possible 6—10 days after the PA banding [46,47]. In similar circumstances, the hybrid approach to stage 1 HLHS palliation may be considered the more prudent approach.

Considering that in most series the highest risk (lowest birth weight, significant extra-cardiac co-morbidities, adverse cardiac variables) patients underwent hybrid palliation, in most reports the results are very good. Whether these variables remain independent risk factors in any surgeon’s/institution’s practice can only be answered by the individual, but in most institutions a subset of patients remains which is high risk for that centre; these patients may benefit from hybrid palliation rather than surgical stage 1.

The hybrid approach is also more flexible than surgery. As such it provides excellent palliation for patients for whom transplantation is considered the most appropriate long-term approach whether through unit policy or for anatomic/functional reasons which preclude a classical approach. In such circumstances the time pressure on procuring a suitable donor heart is relieved and the child is likely to be exposed to fewer blood products making problems with later organ matching less. Likewise, some patients with borderline two ventricle appropriateness either by morphology or function may be palliated using the hybrid approach allowing further development or recovery of cardiac function so that a two ventricle repair may ultimately be performed. While it is possible to take down a Norwood stage 1, this is a much greater undertaking than converting a hybrid procedure.

The question therefore arises as to whether there is a role for surgical stage 1 Norwood palliation in the new era of improved hybrid palliation. Currently the answer is undoubtedly yes. With modern surgical, anaesthetic and intensive care practices, for most patients born with HLHS surgical results to completion of stage 2 palliation are superior to those for the hybrid approach. However, it is clear from the literature that results for both surgery and intervention are very institution dependent. It is therefore not possible to generalise, and each centre must continuously and honestly analyse its own results and conclude from this analysis the appropriateness of each approach for specific patient groups in that institution. Both surgery and interventional techniques are continually evolving and a constant reassessment of each unit’s performance must be undertaken.

In conclusion, the hybrid approach has come a long way from its inauspicious beginning in 1993. Though it is relatively early, current results suggest there are subgroups which are better palliated with this approach than surgery, specifically small premature infants, those with severe co-existing issues, and those with poor ventricular function which may recover and allow a later two ventricle repair. In most institutions surgical results are currently superior for other subgroups of patients. However, as experience in interventional palliation increases, this position will need to be reassessed.

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References
