Complications and lead extraction in cardiac pacing and defibrillation

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The only indications for which lead extraction may be really necessary are infected pacing or defibrillation systems. Superfluous non-functional leads can on the whole be more safely abandoned than extracted. Improvements in lead extraction will be more helped by designing and implanting leads that can be more easily removed than current models, than with better extraction tools. Still, as infection and hence lead extraction usually follows surgical interventions of a pacing or defibrillation system, avoiding the latter – or postponing it if possible – is of great importance (*Neth Heart J* 2008;16 (suppl 1):S28-S31.)

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With the growing number of pacing and defibrillator implantations, it is to be expected that demand for lead extraction will increase as well. As lead extraction has a definite morbidity and mortality it is not only important to delineate the indications and technical requirements, but even more to focus on prevention of complications that precede extraction.

Indications for extraction

The common cited indications for lead extraction are infection and superfluous, abandoned leads (table 1). For the latter indication, there is no solid proof that properly abandoned superfluous leads pose any danger to the patient.[1,2] Likewise, the notion that multiple leads have a higher chance of obliterating the veins has never been substantiated. Of note, occlusion of the access vein is not uncommon: it is present in about 10% of uncomplicated first implants but is mostly asymptomatic. In contrast, there are indications that lead extraction can result in venous obstruction.[2] So, until proof of the contrary, properly abandoning non-functional leads is the safest approach.

In contrast, there is ample evidence that lead extraction is very effective in curing device-related infections. Once infection has become systemic or endocarditis is present, lead extraction is mandatory as the leads themselves are often colonised with bacteria rendering them inaccessible for antibiotic therapy. In selected patients with skin erosions and low-grade infections, conservative therapy will be effective in about one third of patients.[3] Although labelled conservative, treatment often involves extensive debridement of the pocket, relocation of the generator and leads, and irrigating the pocket with a solution containing antibiotics or povidone-iodium.[4,5] Conservative therapy should be reserved for patients with a high risk of lead extraction (long implant times exceeding ten years, elderly patients, multiple leads or no alternative pacing sites). In contrast when leads are implanted for only a few years, the risk of extraction is relatively low and outweighs the risk of recurrent of spreading infection.

The extraction procedure

Scar tissue envelops chronically implanted leads at discrete sites anywhere along the course through the veins or myocardium, and it behaves as if shrink-wrapped around the leads. Therefore, when trying to pull a lead out, any bulge in the lead has to be dragged through that scar. The electrodes make up for most of the protruding parts, especially the flanges of passive fixation leads. Further, indentations in the lead can be filled with fibrous tissue and resist extraction. The ingrowing of this scar in the defibrillation coils is a major problem when extracting ICD leads. Even when leads dislocate from the myocardium, this often leaves a rim of fibrous tissue around the tip, complicating the extraction even more.

Subsequently, just to be able to make room for the bulky distal part of the lead, it is often necessary to disrupt all proximal scar tissue. To achieve this, a variety of sheaths, mechanical or powered, can be inserted

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Table 1. Indications for lead extraction.

Indications reflect the balance between risk and benefit. Leads implanted for only a few years can be extracted with a low risk. Long implant times, dual coil ICD leads, multiple leads and elderly age of the patient increase the risk. Extraction should never be half-hearted or technically insufficiently supported, as this can result in disintegrated or dislocated leads

Mandatory
- Lead-related (right-sided) endocarditis
- Pocket infection with signs or symptoms of systemic infection
- Local infection not responding to conservative therapy

Advisable
- Local infection of a pacemaker or ICD pocket
- Recurrent systemic infection of unknown origin in a pacemaker or ICD patient without signs of pocket infection or lead vegetations

Not advisable
- Superfluous non-functional leads that cannot be easily removed (implanted for longer than 6 to 12 months)

over the lead. However, the superior vena cava has a wall thickness of sometimes less then 1 mm and is vulnerable for damage by the sheaths.[6] Sometimes, the path of least resistance is the vessel wall rather than the scar. Disruption of the superior caval or brachiocephalic vein is the most devastating complication of lead extraction, as it results in swift exsanguination in the thoracic cavity and is very difficult for the surgeon to control or repair.[7]

Damage to the veins can be largely avoided with a femoral approach. With this technique, the leads are first grabbed in the right atrium with a retriever inserted via a sheath introduced through the femoral vein. As the lead body is truly isodiametric, the proximal part of the lead can be often pulled down without excessive force – and without a sheath that directly engages the veins. The sheath is, however, still needed to disrupt the scar tissue from the right atrium down to the atrial or ventricular myocardium. Although this still has a risk of perforation, bleeding will be confined to the pericardial space and is more accessible to control by the surgeon.

When should a patient be referred for lead extraction? Generally, leads that are implanted for less than a year can often be removed by traction alone and the risk of the procedure is limited. If too much resistance is encountered, it is safer to abandon the procedure and refer the patient. From time to time, even leads that have been implanted only recently will necessitate tools to extract them. With longer implant times, it is safer if not mandatory to perform lead extraction in the operating room with cardio-surgical standby as there is often not enough time to transfer a patient before irreversible damage has occurred.[8] This approach will save a life every 100 or 200 procedures.

Lead design and extraction

Lead extraction would be better served by designing and implanting leads that can be easily removed than by improving the extraction technique itself. The profile of an ideal lead should be overall cone-shaped: with every transition in the lead the diameter should decrease slightly, making it easier to pull the lead from and through the scar. Active fixation mechanisms are therefore preferred to avoid the protruding flanges. Dual coil ICD leads should be avoided: the proximal coil is situated in the superior caval vein and highly augments the risk of extraction. Of note, defibrillation thresholds do not differ between single and dual coil leads.[9]

Attempts have been made to make the ICD coils less prone to ingrowing of scar tissue by backfilling the coils, or covering them with a PTFE (Gore®) membrane. It is possible that coating of coils or electrodes, following the same principle as drug-eluting stents, could be very efficient to prevent formation of scar tissue.

Avoiding extractions

The best way to avoid extraction is to avoid infection. Although infection may occur in less than 1% of new implants, the incidence increases to more than 3% for subsequent interventions.[10]

The generator pocket is especially vulnerable when a re-intervention is necessary during the first weeks after surgery. Tissues have become indurated at that time and less well perfused making them prone to colonisation with bacteria.

Re-interventions often follow after dislocation of leads or in the event of a haematoma. To avoid dislocation, we prefer active fixation leads. However, it is imperative that an adequate current of injury is obtained after placing the leads to ensure adequate fixation.[11] Lack of sufficient slack in a lead is another common cause of dislocation, as leads tend to become taut in the upright position and with deep inspiration.

Any haemorrhage increases the risk of infection. Apart from the fact that blood is an ideal culture for bacterial growth, the vitality of the skin overlying a tense haematoma can be compromised, decreasing the

resistance for infection. Finally, wound dehiscence constitutes an obvious port for contamination. Jeopardised skin vitality and threatening dehiscence, apart from pain, necessitate exploration of the pocket to remove the haematoma and establish haemostasis.

To avoid bleeding, meticulous attention should be paid to adequate haemostasis during the procedure. There should be a low threshold to insert a drain in case of dubious haemostasis, or in patients on anticoagulation, especially when it has to be resumed shortly after the procedure. Often the production of a drain may seem 'disappointing', but by creating a vacuum inside the pocket, haemostasis will be promoted.

When a generator has to be replaced, the new one often does not fit very well into the old pocket. Also a slightly different orientation of the generator can cause some redundancy of the leads with pressure on the overlying skin and ensuing skin erosion. This risk increases after substantial weight loss, as often occurs in elderly patients. As a result, generator replacements can be more challenging than new implants. When replacing a generator in such circumstances, one should pay attention to enlarging the pocket, or create a new one when necessary. However, in patients lacking sufficient subcutaneous fat, the capability to create a sub-muscular pocket should be available when exchanging generators.

Reducing the need for surgical intervention will decrease the chance of infection. The most efficient way to accomplish this is through battery longevity. Pacemakers have decreased substantially in size, up to a point where the leads and header have become more bulky than the device. However, battery longevity has remained essentially unaltered, or has even become shorter: not only because of the smaller size, but also from increased current drain from ancillary function.[12] Yet in many patients, larger devices with more than double the battery capacity could be implanted without any discomfort or risk for complications and this would significantly decrease the need for generator replacement. It would also make sense economically as the cost of pacing therapy would be substantially reduced as well.

However, even though patients may prefer longevity above a smaller size, market forces are more focused on size and features than battery longevity. In spite of that, the latter should reside at the top of the wish list when choosing a device.

Not only the size of pacing devices but also that of ICD generators is coming down to a size where one could argue whether patients would be better off with a longer battery life than with a load of features with an often unknown battery drain. This is particularly important for young patients with primary electrical heart disease who face an uncomfortable number of interventions in their lifetime.

A second reason for surgical intervention is lead dysfunction, which often necessitates premature interventions. Lately, this is of greater concern for ICD than pacemaker leads, probably because they have a more complex design and yet are packed in the same

Table 2. Catharina Hospital lead extraction experience from 1997 to June 2008.

	Patients		Technique			Complications	
	Total	ICD	Traction or femoral workstation	Powered sheath: Laser	Powered sheath: Mechanical dilator	Acute surgery	Death
1997	10		2	8			
1998	24	3	2	22		1	
1999	25	7	4	21		1	
2000	28	7	11	17		2	
2001	23	1	13	10		1	
2002	27	1	10	17		6	2
2003	24	3	17	7			
2004	20	3	13	7		3	2
2005	30	6	23	7		3	1
2006	26	3	24	2			
2007	42	4	40		2		
2008	25	6	22		3	1	
Total	304	44	181	118	5	18	5

All numbers refer to patients, not leads: a total of 602 leads were extracted in 304 patients, including 44 patients with an ICD lead. Traction=leads removed from the subpectoral area by simple traction or after insertion of a locking stylet. Femora=leads removed through a 16 F femoral workstation, generally with a Needle's eye retriever (Cook Medical, Bloomington, IN). Powered sheaths=if a powered sheath was used in any of the extracted leads, the patient was categorised as such. Laser=Excimer laser, Spectranetics, Colorado Springs, CO. Mechanical dilator sheath=Evolution, Cook Medical, Bloomington, IN. Acute surgery=all patients had acute surgery for pericardial tamponade or bleeding from caval vein laceration. Death=patients succumbing despite acute surgery. Note that all but one complication resulted from the use of powered sheaths.

slim profile as pacing leads. A recent report estimated an ICD lead survival rate of only 60% after eight years, with no difference between 'older' and 'recent' models.[13,14] It has to be regretted that an independent, prospective follow-up of ICD lead performance is lacking, which would enable an educated choice of reliable lead models. A nationwide prospective registration could be instrumental in such a survey.

A third consideration for intervention is advisories and recalls. It should be noted that ICD generator or lead replacement in patients with advisory devices is associated with a substantial rate of complications, including death, and these often surpass the mortality and morbidity of the potential defect.[10] The same reasoning has to be applied for upgrading existing systems: there should be a clear benefit for the patient that outweighs the risk of an intervention before the end of the life of the present system is reached.

Conclusion

In an ideal world, lead extraction would be an obsolete procedure: there would be no complications of pacing and defibrillator therapy or leads could be easily removed without risk. However in real life, even with the greatest care, complications cannot be avoided but it is necessary to have the risk of complications – and their consequences – in mind when considering device-related interventions. Prevention of pacing and defibrillator complications is the best way to prevent complications of lead extraction. ■

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