Covid a catalyst for change: Expanding your dialysis access options

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Disclosure

Speaker name:
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I have the following potential conflicts of interest to report:

☒ Consulting BD Bard
☐ Employment in industry
☐ Stockholder of a healthcare company
☐ Owner of a healthcare company
☐ Other(s)

☐ I do not have any potential conflict of interest
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The clinicians have been compensated by Becton, Dickinson and Company to participate in this presentation.
David Maguire, a senior analyst at the King’s Fund, said: “The impact of Covid-19 on waiting times will be felt for years to come. Despite the best efforts of staff there simply isn’t the capacity to get through the backlog quickly.”

Headlines from around the world

Covid’s ‘devastating impact’ on NHS services exposed by latest figures

Number of patients on waiting lists for more than a year is 123 times larger than 2019

Hospitals across US cancel elective procedures- again

Germany was held up as an example of how to do the pandemic. Now it’s struggling.

France’s ‘Plan Blanc’- Paris and Marseille Hospitals scheduled operations on hold to free up space

4. https://www.washingtonpost.com/gdpr-consent/?next_url=https%3a%2f%2f%3Ca%20href=
69% of surgeons highlighted a lack of theatre capacity as a significant barrier to resuming planned procedures.

<table>
<thead>
<tr>
<th>Issue</th>
<th>Percentage</th>
</tr>
</thead>
<tbody>
<tr>
<td>Lack of theatre capacity</td>
<td>69.4%</td>
</tr>
<tr>
<td>Lack of staff</td>
<td>52.9%</td>
</tr>
<tr>
<td>Lack of sufficient PPE</td>
<td>38.2%</td>
</tr>
<tr>
<td>Lack of access to fast testing for patients</td>
<td>37.8%</td>
</tr>
<tr>
<td>Lack of critical care beds</td>
<td>16.5%</td>
</tr>
<tr>
<td>Lack of capacity in independent services</td>
<td>5.4%</td>
</tr>
</tbody>
</table>
Surgical facilities will be strained – GLOBALSURG 1st wave

Elective surgery cancellations due to COVID-19 pandemic: Global predictive modelling to inform surgical recovery plans

- 28.4 MILLION
  Operations will be cancelled or postponed during the peak 12 weeks of disruption

- 2.3 MILLION
  Cancer surgeries will be cancelled or delayed

- 72.3%
  Of operations will be cancelled

- Highest cancellation rate
  Benign disease
  Orthopedics

UNITED KINGDOM
- 516,000
  (36,000 Cancer)
  Cancelled Surgeries

CLEARING BACKLOG WILL TAKE
- 11 Months
- 20% Extra Activity
- 2 Billion

CONCLUSION
- Country level data will inform system planning to recover after the pandemic

Challenging discussions about what surgery takes priority are occurring already

How vascular services have been affected during COVID in Asia

Patients requiring surgery during the COVID-19 crisis have been classified in the following groups (NHS):

- Priority level 1a Emergency - operation needed within 24 hours
- Priority level 1b Urgent - operation needed with 72 hours
- Priority level 2 Surgery that can be deferred for up to 4 weeks
- Priority level 3 Surgery that can be delayed for up to 3 months
- Priority level 4 Surgery that can be delayed for more than 3 months
<table>
<thead>
<tr>
<th>Timeframe</th>
<th>Condition Description</th>
<th>Additional Details</th>
</tr>
</thead>
<tbody>
<tr>
<td>1a. Emergency (24hrs)</td>
<td>Vascular injury/ occlusion (Limb - including compartment syndrome and GIT)</td>
<td>Uncontrolled external haemorrhage - any site/source</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Ruptured AAA</td>
</tr>
<tr>
<td>1b. Urgent (up to 72 hrs)</td>
<td>Acute on chronic limb ischaemia Amputation for limb ischemia</td>
<td>Symptomatic carotid disease</td>
</tr>
<tr>
<td></td>
<td></td>
<td>?Clotted access Risk of rupture / aneurysm</td>
</tr>
<tr>
<td>2. Up to 1 month</td>
<td>Chronic severe limb ischaemia - no neurology</td>
<td>AAA &gt;7cms diameter</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Dysfunctional Access</td>
</tr>
<tr>
<td>3. Up to 3 months</td>
<td>AAA &gt;5.5cm and &lt;7cm diameter</td>
<td>Vascular access creation</td>
</tr>
<tr>
<td>4. Over 3 months</td>
<td>Vein surgery</td>
<td>Thoracic outlet syndrome</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Claudication</td>
</tr>
</tbody>
</table>

## SVS Covid Guidance

<table>
<thead>
<tr>
<th>Category</th>
<th>Condition</th>
<th>Tier Class</th>
</tr>
</thead>
<tbody>
<tr>
<td>Dialysis</td>
<td>Thrombosed or non-functional dialysis access</td>
<td>3 Do not postpone</td>
</tr>
<tr>
<td></td>
<td>Infected dialysis access</td>
<td>3 Do not postpone</td>
</tr>
<tr>
<td></td>
<td>Fistula revision for ulceration</td>
<td>3 Do not postpone</td>
</tr>
<tr>
<td></td>
<td>Renal failure with need for dialysis access</td>
<td>3 Do not postpone</td>
</tr>
<tr>
<td></td>
<td>Tunnelled Dialysis Catheter</td>
<td>3 Do not postpone</td>
</tr>
<tr>
<td></td>
<td>Fistula revision for malfunction/steal</td>
<td>2b Postpone if possible</td>
</tr>
<tr>
<td></td>
<td>Fistulagram for malfunction</td>
<td>2b Postpone if possible</td>
</tr>
<tr>
<td></td>
<td>AV fistula and graft placement for dialysis (ESRD, CK4 and CK5 only)</td>
<td>2a Consider postponing</td>
</tr>
</tbody>
</table>

Solutions

1. Compete with other surgical procedures
   (Surgical VA Creation is given priority over cancer/AAA/CI etc.)

2. Increase surgical resources

3. Use CVCs and delay Surgical VA

4. Use an alternative route of VA creation
Managing surgical and endovascular workload during a protracted COVID-19 outbreak also involves searching for innovative solutions. Therefore, a great proportion of fistula creation or reconstruction should be switched toward minimally invasive strategies, preferably percutaneous, in both the elective and emergency setting. Maintenance percutaneous transluminal angioplasty reduces the thrombosis rate and
Proposal: EndoAVF

Where surgical facilities are limited

Avoid CVC
Maintain VA rates
Decrease Hospitalizations
Reduce overall risk to dialysis patients
Economic benefits of avoiding CVC
Optimize facilities
Discussion

• Surgical AVFs are far from perfect
  • Poor maturation
  • High rates of CVC use
  • Maintenance requirements
  • Complications

“The impact of Covid-19 on waiting times will be felt for years to come. “The King’s Fund”

• Covid could be a catalyst for change:

• Expanding dialysis access options to include endoAVF creation

Indications: The WavelinQ™ 4F EndoAVF System is intended for the cutting and coagulation of blood vessel tissue in the peripheral vasculature for the creation of an arteriovenous fistula used for hemodialysis.

Contraindications: Known central venous stenosis or upper extremity venous occlusion on the same side as the planned AVF creation. Known central venous stenosis or upper extremity venous occlusion on the same side as the planned AVF creation. Known allergy or reaction to any drugs/fluids used in this procedure. Known adverse effects to moderate sedation and/or anesthesia.

Distance between target artery and vein > 1.5 mm. Target vessels < 2 mm in diameter.

Warnings: The WavelinQ™ 4F EndoAVF System is only to be used with the approved commercially available devices specified in the IFU. Do not attempt to substitute non-approved devices or use any component of this system with any other medical device system. The WavelinQ™ 4F EndoAVF System catheters are single use devices. DO NOT re-sterilize or re-use either catheter. Potential hazards of reuse include infection, device mechanical failure, or electrical failure potentially resulting in serious injury or death. Use caution when performing electrosurgery in the presence of pacemakers. Improper use could damage insulation that may result in injury to the patient or operating room personnel. Do not plug device into the electrosurgical pencil with ESU on. Keep active accessories away from patient when not in use. Do not permit cable to be parallel to and/or in close proximity to leads of other devices. Do not wrap cable around handles of metallic objects such as hemostats. Consult the ESU User’s Guide on its proper operation prior to use. Do not use closure devices not indicated to close the artery used for access.

Caution: Only physicians trained and experienced in endovascular techniques should use the device. Do not kink, pinch, cut, bend, twist, or pull excessively or with excessive force on any portion of the devices. Damage to the catheter body may cause the device to become inoperable. Avoid sharp bends. This may cause the device to become inoperable. Do not pinch or grasp the catheter with excessive force or with other instruments. This may cause the device to become inoperable. Do not bend the rigid portion of the catheter near the electrode or backstop. Do not touch or handle the active electrode. Electrode dislodgement may occur. Always use the hemostasis valve crosser to assist insertion of the venous catheter through the introducer sheath. Insertion into the introducer sheath without hemostasis valve crosser may damage electrode. Do not attempt to remove the hemostasis valve crosser located on the venous device. Device damage or fracture may occur.

Precautions: Care should be taken to avoid the presence of fluid on the ESU. Care should be taken during handling of the arterial and venous catheters in patients with implantable cardiac defibrillators or cardiac pacemakers to keep the distal 3 inches of the catheters at least 2 inches from the implanted defibrillator or pacemaker. Care should be taken to avoid attempting fistula creation in a heavily calcified location of a vessel as fistula may not be adequately formed. If the device does not perform properly during the creation of the endovascular fistula it is possible that a fistula will not be created or there may be some vessel injury. Keep magnetic ends of catheters away from other metallic objects which may become attracted and collide with devices.

Potential Adverse Events: The known potential risks related to the WavelinQ™ 4F EndoAVF System and procedure, a standard AVF, and endovascular procedures may include, but are not limited to: aborted or longer procedure; additional procedures; bleeding, hematoma, or hemorrhage; bruising; burns; death; electrocution; embolism; failure to mature; fever; increased risk of congestive heart failure; infection; numbness, tingling, and/or coolness; occlusion/stenosis; problem due to sedation or anesthesia; pseudoaneurysm; sepsis; steal syndrome or ischemic swelling, irritation, or pain; thrombosis; toxic or allergic reaction; venous hypertension (arm swelling); vessel, nerve, or AVF damage or rupture; wound problem.

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