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VP120 A United Kingdom Research Commissioning Framework For Devices And Diagnostics

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INTRODUCTION:

Generation of high-quality evidence on medical devices through clinical trials can be challenging. The United Kingdom's National Institute for Health and Care Excellence (NICE) has developed a research commissioning framework for producing clinical evidence where gaps in the literature prevent definitive recommendations in their medical technology guidance and diagnostics guidance. The research commissioning framework involves NICE's external assessment centers collaborating with clinical researchers to secure funding and to design, conduct, and publish a study to address research recommendations within 3 years of guidance publications. We aimed to describe the early results of the framework.

METHODS:

Publically available information and results from an informal survey of NICE's external assessment centers were reviewed.

RESULTS:

As of December 2016, NICE has published a total of thirty medical technology guidance topics and twenty-four diagnostics guidance topics, five and twenty of which have research recommendations, respectively. A total of fourteen research commissioning framework-facilitated projects have been initiated. Two research projects have successfully secured external funding for a clinical trial: (i) non-contact low frequency ultrasound therapy for wound healing; and (ii) Parafricta bootees for pressure ulcer prevention. Further projects have produced published outputs without external funding. Four projects have been completed and undergone guidance review; one guidance topic was withdrawn and three have been transferred to the "static list". Early experiences of NICE's research commissioning framework suggest that securing financial support from manufacturers or funding bodies for interventional clinical trials to answer single technology research questions within a short time frame is challenging but possible. The value of early feasibility studies to assess the likelihood of obtaining funding and of addressing NICE's research recommendations was recognised.

CONCLUSIONS:

NICE can facilitate independent research through its research commissioning framework initiative. Securing funding has proved challenging but recent successes have shown that approach is possible. Outputs which fill the evidence gap to an extent where a definitive guidance update is possible have been rare.

VP122 Cryoballoon Versus Radiofrequency Ablation For Atrial Fibrillation

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INTRODUCTION:

Pulmonary vein isolation (PVI) is a new effective treatment for atrial fibrillation (AF) (1). The standard of care for ablation methods using radiofrequency (RF) is time-consuming and technically challenging (2), and restricted to a few specialized centers, which causes the limited availability of ablation therapy (3). Therefore, cryoballoon (CB) ablation has been developed to

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shorten and simplify the procedure. The objective of this systematic literature review and meta-analysis was to compare the effectiveness of cryoballoon ablation (CBA) with radiofrequency ablation (RFA) for the treatment of AF.

METHODS:

We searched the Cochrane Library and PubMed from 2009 to October 2016 to screen the eligible literature according to the inclusion and exclusion criteria. The effectiveness measures were the acute pulmonary vein (PV) isolation rate, procedure time, complications and the proportion of patients free from AF (follow-up $>$ 3 months). Meta-analysis and descriptive statistics were used in this study.

RESULTS:

A total of seventeen articles with 5,806 cases (2,288 from CBA group, 3,518 from RFA group) from seven different countries were reviewed and analyzed. Pooled analyses indicated that CBA was more beneficial in terms of procedural time (Standard mean difference, SMD = -.501; 95%CI: -.893– -.109; P$<$.05) for RFA; but the acute PV isolation rate (Odds ratio, OR = .06; 95 percent Confidence Interval, CI: .03–.13; P $<$ .05) in RFA was higher than for CBA; also, after median follow-up of 14 months (range 9–28 months), the proportion of patients free from AF (OR = .965; 95 percent CI:.859—1.085; P = .554) and the total complication rates (OR = .937; 95 percent CI:.753–1.167; P = .562) were not significantly different between CBA and RFA.

In the four randomized controlled trials (RCTs) of the seventeen studies, the proportion of patients free from AF (OR = .951; 95 percent CI:.752–1.202; P = .672) and the complications (OR = 1.521; 95 percent CI:.570–4.058; P = .402) were not significantly different between CBA and RFA.

CONCLUSIONS:

Overall, compared with RFA for the treatment of patients with AF, CBA had similar clinical effectiveness on the proportion of people free from AF and the number of complications, and yet greater improvement in total procedure time referred for CBA and higher acute PVI rate referred for RFA.

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VP124 The End Of A French Medical Dogma For Hepatitis B And C Diagnosis

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INTRODUCTION:

Since the 1990s in France, based on contemporary French consensus conferences, for Hepatitis B (HBV) or Hepatitis C (HCV), diagnosis is acknowledged when detection of Hepatitis B surface antigen or anti-HCV antibody is positive on a 1st test line and further replicated on an independent blood sample.

The replication was introduced to alleviate the low performance of immunoassay and avoid false positive results.

Currently, the Haute Autorité de santé (HAS) is managing an update of diagnostic tests reimbursed for HBV and HCV to fully cover diagnostic needs.

Our aim is to assess the clinical relevance of this repetition.

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