## Evaluation of the Fukuoka Consensus Guidelines for intraductal papillary mucinous neoplasms of the pancreas: Results from a systematic review of 1,382 surgically resected patients

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**Background.** International consensus guidelines to guide management of intraductal papillary mucinous neoplasms (IPMN) were revised in Fukuoka and published in 2012. However, despite widespread acceptance of the Fukuoka Consensus Guidelines (FCG), the utility of these guidelines have not been well-validated. This systematic review was performed to evaluate the clinical utility of the FCG.

**Design.** A computerized search of the PubMed and Scopus databases was performed to identify all studies evaluating the utility of the FCG in surgically resected IPMN. IPMN were stratified according to the FCG as high risk (HR), worrisome risk (WR), and low risk (LR). HR and WR IPMN were termed FCG+ve and LR IPMN were termed FCG-ve.

Results. Seven studies analyzing 1,382 patients were included. There were 402 malignant neoplasms (29%), including 242 invasive IPMNs. There were 1,000 IPMN classified as FCG+ve. The FCG+ve group had a positive predictive value (PPV) ranging from 27 to 62% and the FCG-ve group had negative predictive value ranging from 82 to 100%. Pooled analysis demonstrated that there was 362 of 1,000 (36%) malignant FCG+ve IPMN and 342 of 382 (90%) benign FCG-ve IPMN. PPV of the HR group and the WR groups alone were 104 of 158 (66%) and 75 of 261 (29%), respectively. Forty of 382 (11%), including 22 (6%) invasive FCG-ve IPMN, were malignant. Twenty-six malignant including 18 invasive FCG-ve IPMN were reported from a single study. When the results from this study were excluded, there were only 14 of 241 malignant neoplasms (6%), including 4 of 241 (2%) invasive FCG-ve IPMN in the remaining 6 studies.

Conclusion. The FCG+ve criteria had a similarly low PPV compared with the 2006 consensus criteria. Stratification of IPMN into HR and WR groups resulted in a higher PPV in the HR group. Some malignant and even invasive IPMN may be missed by the FCG criteria. (Surgery 2015;158:1192-202.)

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PRESENTLY, THE MANAGEMENT APPROACH TO INTRADUCTAL PAPILLARY MUCINOUS NEOPLASMS (IPMN) remains controversial. In general, the management of IPMN has trended from an aggressive resection approach to a more conservative approach.<sup>1-4</sup> The more conservative approach has been increasingly adopted by clinicians owing to the improved knowledge of the pathology and natural history of these neoplasms. 4-7 At present, it is widely accepted that main duct (MD)-IPMN and mixed type (MT)-IPMN should generally be resected whereas selected branch duct (BD)-IPMNs may be observed.<sup>2,8</sup> This is because MD- and MT-IPMN are associated with an increased risk of malignancy of between 40 and 92%<sup>2,8-10</sup> compared with BD-IPMN, which harbors a risk of malignancy in approximately 15–25% of cases.<sup>9,10</sup>

In 2006, an international consensus panel of experts convened in Sendai and published recommendations for the management of IPMNs and mucinous cystic neoplasms.<sup>2</sup> These guidelines became commonly known as the Sendai Consensus Guidelines (SCG; Table I). The guidelines recommended that all mucinous cystic neoplasms and MD/MT-IPMN should be resected whereas selected BD-IPMN, which did not meet criteria could be managed via surveillance. However, these guidelines were limited by its low positive predictive value (PPV), which resulted in a large number of benign BD-IPMN being resected.<sup>4</sup> Hence, the SCG was subsequently revised in 2010 in Fukuoka. The updated guidelines termed the Fukuoka Consensus Guidelines (FCG) in this study

were published in 2012 (Table I).<sup>8</sup> The main revision to the guidelines was that IPMN was now stratified into 3 instead of 2 different risk groups. The updated guidelines recommended resection for the high-risk (HR) group and surveillance for the low-risk (LR) group. Endoscopic ultrasonography (EUS) was recommended for the intermediate risk group, which is termed worrisome risk (WR) in this study. Two important changes made to the guidelines were that cyst size >3 cm alone was no longer a definitive criterion for upfront resection (with the caveat that surgery should be considered in fit patients) and only symptoms such as jaundice and/or pancreatitis were included as criteria in the updated guidelines.

It is important to highlight that the FCG, like the earlier SCG, was formulated based on expert opinion after extensive literature review<sup>11-13</sup> and not on robust clinical data.4 Hence, despite its increasing widespread acceptance, there are limited data to date supporting its utility. A recent systematic review of 690 patients from 9 studies validating the original SCG reported that the SCG was associated with a low PPV and despite its high negative predictive value (NPV); some malignant IPMN could be missed.<sup>4</sup> The investigators from Heidelberg also generated much controversy when they published their findings reporting that ≤25% of suspected BD-IPMN that did not meet SCG criteria for resection were malignant and 16% were invasive. 4,10,14-16

Because the FCG was published recently (in 2012), thus far there have been limited studies

Table I. Summary of the Sendai Consensus Guidelines and Fukuoka Consensus Guidelines

Guideline	Criteria
SCG	
MD-IPMN	$MPD \ge 10 \text{ mm}$
SCG+ve BD-IPMN	Size $> 3$ cm
	Size $\leq 3$ cm with symptoms/mural nodules/MPD dilation (>6 mm)/positive cytology
FCG	
High-risk features	Proximal lesion with obstructive jaundice
	Enhancing nodules
	Dilated main duct (≥10 mm)
Worrisome risk features	$Size \ge 3 cm$
	Pancreatitis
	Nonenhancing nodules
	Thickened, enhancing walls
	Dilated duct (5 to <10 mm)
	Change in duct caliber with distal atrophy
	Lymphadenopathy

BD-IPMN, Branch duct intraductal papillary mucinous neoplasm; FCG, Fukuoka; MPD, main pancreatic duct; MD-IPMN, main duct intraductal papillary mucinous neoplasm; SCG, Sendai Consensus Guidelines.

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