BIG DATA IN ASIA-PACIFIC - A VALUABLE RESOURCE FOR BETTER HEALTH CARE DECISIONS:

EXPERIENCES AND LESSONS LEARNED IN JAPAN

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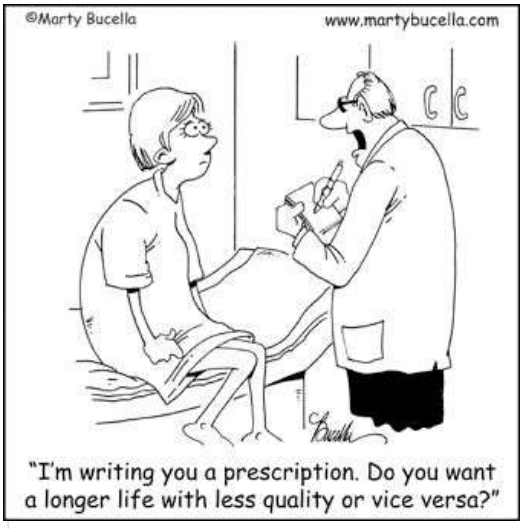
Real-world data for real-world decisions



- RWD is being used to answer a plethora of health care questions in Japan
  - Burden of disease
  - Cost-effectiveness
  - Risk of disease / adverse effect
  - Understanding trial results
  - Treatment patterns
  - Safety evaluations
  - Trial simulations
- Methods within Japan have been improving

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Putting trial results into context

- An increased risk of adverse events was found in clinical trials
- Little known about the underlying rate of events in the general disorder compared to non-disorder patients in Japan
- Conducted a database analysis to evaluate rate of events in the general disorder population and matched non-disorder patients
- Simulated trial results to understand what the rate would be in “trial like” patients in Japan
  - Following inclusion / exclusion criteria, a random selection of patients was generated to match the same gender distribution and same age (SD)

Retrospective DB analysis provided the underlying background rates of events in a Japanese population. By simulating a trial population, expected “natural” even rates could be compared with trial data.

Increasing chances of success

- Infection rates were well studied in the US / EU where trials were being designed
- Same protocol was to be used in Japan
  - Risk of failed trial if rates are different
- Using a retrospective database, key populations were identified where the risk of infection was higher
  - Results compared to Global protocol to evaluate appropriateness of joining Global trial

The evaluation of patient populations through retrospective DB allows the identification of key populations to be included in trials, ensuring enough events of interest to show differences

Evaluation of risks

Risk of CVD for Japanese RA patients

- MDV database utilized (April 2011 – March 2014)
- High CVD risk in Western patients but not well documented in Japan
- OA used as a comparator as inflammation is limited to the joints and not systemic like RA
- OA and RA share similar lifestyle risk factors associated with CVD
- Significant increase in CVD risk found in Japanese RA patients

Table 2 Incidence rate ratios of cardiovascular disease

	RA patients (N = 8658)		OA patients (N = 32,202)		RA versus OA	
	Events	PYs at risk	Events	PYs at risk	Crude IRR (95 % CI)	Adjusted IRR* (95 % CI)
CVD (total)	673	10,946	1633	43,304	1.62 (1.49–1.78)	2.12 (1.93–2.32)
Ischemic heart disease	260	11,280	586	44,591	1.73 (1.50–2.01)	2.16 (1.86–2.50)
Myocardial infarction	53	11,481	71	44,574	2.90 (2.03–4.14)	3.62 (2.52–5.18)
Angina pectoris	224	11,319	528	44,138	1.65 (1.41–1.93)	2.05 (1.75–2.40)
Heart failure	358	11,234	808	44,003	1.74 (1.53–1.97)	2.34 (2.07–2.65)
Stroke	177	11,396	513	44,286	1.34 (1.13–1.59)	1.68 (1.41–2.00)
Cerebral infarction	136	11,433	431	44,327	1.22 (1.01–1.48)	1.56 (1.29–1.90)
Intracerebral hemorrhage	32	11,506	77	44,599	1.61 (1.07–2.43)	1.85 (1.22–2.81)
Subarachnoid hemorrhage	15	11,517	15	44,626	3.87 (1.89–7.93)	4.45 (2.13–9.26)

RA rheumatoid arthritis, OA osteoarthritis, PYs patient-years, IRR incidence rate ratio, CI confidence interval, CVD cardiovascular disease

* Adjusted by age and sex

Tanaka *et al. SpringerPlus* 2016; 5: 1111

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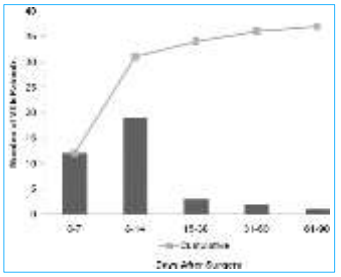
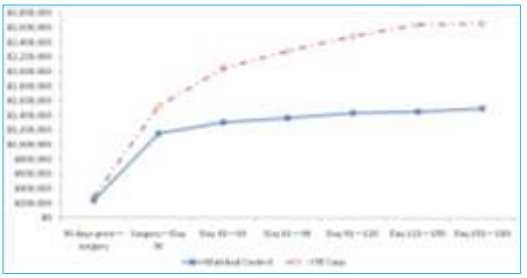
Understanding current epidemiology and developing evidence

Using databases to evaluate event rates

Evaluate the incidence, time course and costs of VTE following major orthopedic surgery





Economic Impact of Venous Thromboembolism Following Major Orthopaedic Surgery in Japan

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Evaluation of treatment patterns and guideline adherence

- 33,325 patients with high cholesterol at high CV risk
- Treatment pattern evaluations in relation to Japan Atherosclerosis Society (JAS) guidelines
  – Statins 1st line therapy
- Only 45% of population treated with lipid-management therapy
- Guideline goal attainment low
- Patients with very high LDL-C levels not adequately treated

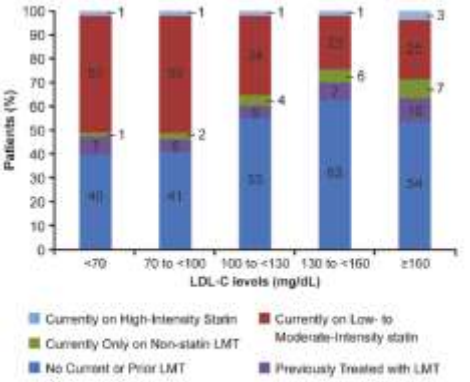

Fig. 3. LMT utilization by LDL-C levels. LDL-C, low-density lipoprotein cholesterol; LMT, lipid-modifying treatment.

Teramoto *et al. Artherosclreosis* 2016; 251: 248-254

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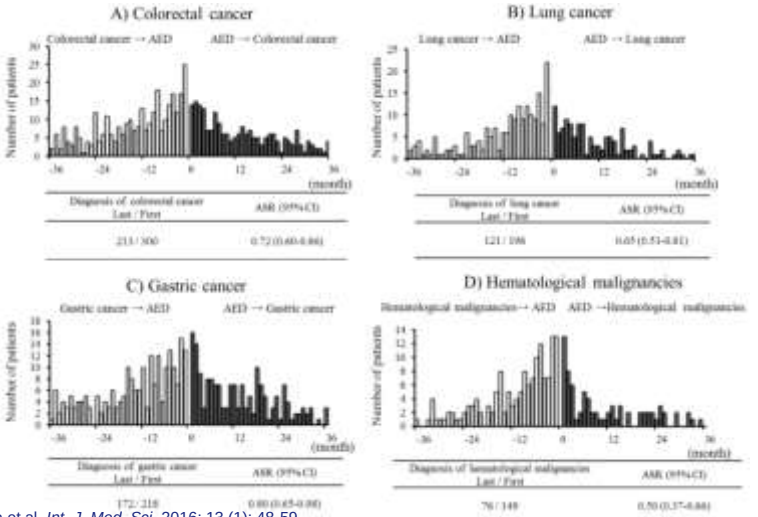
Anti-epileptic treatments and cancer risk

Sequence symmetry analysis



Tanaka et al. *Int. J. Med. Sci.* 2016; 13 (1): 48-59

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