Abstract / Povzetek predavanja

The results of H pylori test and treat implementation studies in Slovenia and EU (EUROHELICAN WP 4, TOGAS WP 4 Study 1)

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BACKGROUND

Helicobacter pylori (*H pylori*)is class I carcinogen (1), responsible for 89% of non cardia gastric cancer (2). Infection is clinicaly silent in majority of those infected and can cause peptic ulcer, *H. pylori*-related dyspepsia, iron deficiency anaemia, idiopathic thrombocytopenic purpura, mucosa-associated lymphoid tissue lymphoma and gastric cancer at some point in the life in 20% of infected individuals (3). The Kyoto Global Consensus on *H pylori* gastritis supports the treatment of all patients with *H pylori* infection, regardless of clinical symptoms (4). Recently IARC Working Group Reports No. 12 as a part of EUROHELICAN project implement guidance on Population-based *H pylori* screen-and-treat strategies for gastric cancer prevention (5).

AIM

EUROHELICAN project in WP 4 implemented for the first time in Europe *H pylori* screen and treat aproach in a young asymptomatic random sample of citizens from 30 -34 years of age in collaboration of National Institute of Public Health (NIPH) and Community Health Center dr Adolf Drolc (CHC) Maribor. In TOGAS project the same principle was introduced in six EU countries and the study is still ongoing.

PATIENTS AND METHODS

In EUROHELICAN 5500 asymptomatic individuals 30-34 years of age were invited to participate (randomised sample). Aditional 769 participants were included (nonrandomised group). The *H pylori* test-and-treat program was free of charge for all eligible participants. Locally validated *H. pylori* IgG serology and UBT as a confirmatory test were used. Quadruple bismuth based 14 day eradication therapy was the first line therapy. RED Cap IT platform (pretreatment questionnaires, treatment protocols, side effects, compliance, complications...) was used to collect data for quality assurance, monitoring, and evaluation.

Four different locally validated *H. pylori* IgG serologies and / or UBT as a test were used in TOGAS project. Quadruple bismuth based 14 day, a 10-day regimen with esomeprazole combined with bismuth quadruple therapy in a single-capsule or 14 day triple eradication therapy were used as the first line therapy.

RESULTS

In EUROHELICAN project the response rate to the written postal invitation was 24%; in men 21.7% and 29.7% in women ($p<0,001$). Gender and age distribution were similar in both study arms. There were in total of 2,105 persons who at minimum

conducted a partial interview with the registered nurse. The *H pylori* seropositivity rate was 13,6% in randomised sample, 15,1% in nonrandomised sample and 14,2% in combined sample. Higher seropositivity rates was found in immigrants (36%,) and those participants whose highest finished level of education was a 2-year vocational school (33.3%, P >0,001). The dropout rate of -22.8% was recorded for participants with a positive serology who should continue with a confirmatory UBT. Second highest dropout rate of -19,9% was recorded for participants with a positive UBT result who were referred to treatment (12 pregnant women not included). Among the patients with a positive UBT 80.1% of total and 85.6% of randomised sample, respectively, initiated eradication therapy. Patients' adherence towards treatment was 90.6%. The rate of reported adverse events was 35.9%, The most frequently reported symptoms were nausea, diarrhoea and abdominal pain. More men reported the absence of adverse events during therapy compared to women (76.5% versus 54.5%, respectively, p= 0.014). The eradication rate for 92 patients who concluded the therapy and were retested by UBT was 95,7%.

The TOGAS study is still ongoing. Interim results show a wide variation of response rates to the invitation (from 4,1% in Wroclaw to 45,5% in Ljubljana). *H pylori* seropositivity / UBT rates vary from 13,9% in Ljubljana to 49% in Latvia. The eradication rates are from 88,2% in Dublin to 96,9% in Ljubljana. No serious adverse events have been reported so far. The differences among study sites are in the organization of invitations, educational campaigns and dissemination activities as well as in the time when study was launched in a certain country.

DISCUSSION

A systematic review of randomized controlled trials of population-based *H. pylori* screen-and-treat strategies in healthy *H. pylori*-positive individuals showed that *H. pylori* eradication was associated with a 36% reduction in risk of developing gastric cancer. In *H. pylori*-positive patients with gastric neoplasia undergoing endoscopic resection *H. pylori* eradication was associated with a 48% reduction in risk of recurrent gastric cancer (6). The available evidence from clinical trials also indicates that *H. pylori* eradication reduces the incidence of dyspepsia and reduces health-care costs (7). In addition, *H. pylori* eradication therapy does not appear to increase the risk of oesophageal cancer or reflux symptoms (6).

CONCLUSION

The combined use of primary *H pylori* serology testing and confirmatory UBT showed no evident shortcomings. The use of quadruple bismuth-based treatment scheme showed encouraging eradication and adherence rates, whereas the incidence of adverse events due to this therapy was within the acceptable range. Specific software/application should be created and integrated into existing information technology (IT) structures of the primary health care system to digitally support the process of preventive testing and treatment. Education and public awareness campaign to increase the participation rate are of crucial importance. Careful study planning: legal, financial, technical, organisational aspect and public awareness campains should be implemented before lounch of the study.

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