The real world data of one year post Taiwan's national health insurance DAA reimbursement for chronic hepatitis C : an experience from primary care clinic

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Objectives: Direct antiviral agent for chronic hepatitis C therapy is reimbursed by Taiwan National Insurance since Jan 24, 2017. Most real world data reported in Taiwan came from Medical Center or Regional Hospital. We report the first real world data from primary care clinic in Taiwan.

Aims: The therapeutic efficacy of direct antiviral agent for chronic hepatitis C has been well established In several clinical trials. However, the effectiveness of these therapeutic modalities have not been verified by real-world practice in Taiwan. We would like to analyze the effectiveness of these new drugs for therapeutic effectiveness in a primary care setting.

Method: From January 24th 2017, 42 patients with F3 or F4 liver fibrosis but without liver decompensation were enrolled and then registered in the care system of Taiwan National Health Insurance. There were only three direct antiviral agent combinations reimbursed by Taiwan National Health Insurance: daclatasvir/asunaprevir, Paritaprevir/Ritonavir/Ombitasvir/ dasabuvir and elbasvir/grazoprevir. All patient was treated with one of these combinations according to their own situation by the same physician. Viral load was recorded before treatment, on the 4th week, the end of treatment and 12 week post treatment. Total bilirubin /direct bilirubin, GOT/GPT were recorded every one or two week during the first 8 week treatment to detect the the time to peak level.

Result: Enrolled patients were 63~72 years old. Gender distribution was even. In the DUAL group, 26 patients were treated to 24W in which SVR12 data were availabıe for 2 patients. In the ProD group, 16 patients were treated to 12W in which SVR12 data were available for 5 patients. HCV RNA was under LLOQ in 23/26(88. 4%) and 16/16 (100%) at Week 4 in DUAL group and ProD group, respectively. EOT is still in progress and was achieved by 4/4 (100%) with DUAL and 14/14 (100%) with ProD. The SVR12 was 2/2 (100%) of DUAL for 24 weeks and 5/5 (100%) of ProD for 12 weeks. Patients received DUAL were older and with worse fibrosis status, making physician more cautious in selecting therapeutic regimen. The average age in DUAL group was 70. 5 years old versus 67. 6 years old in ProD group. FIB-4 was 5.22 in DUAL group and 4.93 in ProD group. Drop out was similar in ProD group, 1/16 (6. 25%) versus 2/26 (7. 6%) in DUAL group. A 89-year-old experienced unbearable fatigue with ProD and quit from therapy on week 1. One patient with newly found hepatoma expired in DUAL group due Io EV bleeding on week 1. Another case withdrew from treatment due to psychological problem, easy agitation, on week 14.

The average of max total bilirubin of ProD group was 1.27mg/dL whereas 0.79mg/dL in DUAL group. The maximal direct bilirubin level recorded was 0. 25 mg/dL in ProD group and 0.2 mg/dL in DUAL group. We analyzed the pattern of bilirubin elevation. The max bilirubin level occurred at 4.12 weeks of ProD initiation and 4.66 weeks of DUAL. As for ALT elevation, the mean max ALT was 48.06 mg/dL in DUAL group and averagely occurred at 7.1 weeks. On the other hand, it was 26.36 IU/ml and 5 weeks in ProD group.

Conclusions: It is the first report from primary care institution in Taiwan about the effectiveness and safety for these new generation antiviral agents in chronic hepatitis C treatment. Bilirubin elevation took place earlier and more frequent in patient treated with ProD regimen. Physician tend to select DUAL regimen for elderly patient due to safety concern.