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P-01

New reports of curcumine-induced hepatitis

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Curcuma is an herbaceous plant of the Zingiberaceae family; it's widely used in the south eastern cuisine. And as a spice in the Indian cuisine as well. Curcuma is also known as the Saffron of Indies.

It is currently believed that this spice stimulates the immune system and carries out anti- tumor, anti- oxidant and anti- inflammatory activity.

There is increasing evidence in literature of hepatitis associated with curcuma intake: to date up to ten cases of cholestatic hepatitis have been reported.

Recently 4 patients, aged 25–45 years, 3 females and 1 male, referred to our medical observation. Hypertransaminasemia up to 3–6 times with respect to normal value, and increasing of gamma-GT up to 4–8 times the norm were found. Only one of 4 cases had a failure of hepatic coagulation factors. Hepatocytonecrosis and cholestasis regressed after the spice withdrawal. Only in one case hepatitis lasted for 20 days.

The etiopathogenesis of acute hepatitis associated with curcuma intake has not yet been clarified; autoimmunity has also been supposed.

We suggest to deep knowledge on the role of contaminants or any kind of agents used for cultivation, storage and transport, and to investigate the role of Gut Microbiota.

It would be advisable to make the general practitioner and the nutritionist aware of refraining from prescribing curcuma until definitive clarification of safety.

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P-02

Social and labor market reintegration of the transplanted patient

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Introduction: The number of working-age patients with organ failure undergoing solid organ transplantation is presently increasing, posing important problems with reintegration in society and the workplace. The Project "*Development of a multidisciplinary network and Web Applications to encourage the adoption of healthy lifestyle, overcoming psychological barriers and encourage the return-to-work of transplanted patients*" aims to provide tools that facilitate

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the psychophysical recovery and return-to-work of transplanted patients, through the prescription of physical activity as non-pharmacological therapy.

Aim: The two-year project will study the effects of regular physical activity on a sample of 100 working-age transplanted patients. Two different IT systems will be developed: an APP aimed at recording the activity performed by the patients and a Web Application that could support Transplant Centers' clinicians, Sports medicine Doctors, and occupational physicians in the evaluation of patients' health status for their return to work.

Materials and methods results: The APP will record the activity performed by the patients enrolled in the study whereas the Web Application will collect further information related to the return-to-work of transplanted patients, through the submission of questionnaires to patients, doctors, workers, companies, employment agencies, but it will also offer to the National Transplant Network the possibility to have free access to scientific literature and support clinicians in the evaluation of the effects of physical activity in transplanted subjects, building a network of experts who, with different levels of responsibility, follow the path of the transplanted patients' returning to work.

Conclusions: The project, led by the Italian National Transplant Center as part of a six-partner consortium, is funded by the National Institute for Insurance against Work Accidents. In two years, it aims to build a multidisciplinary network to support the social and labor reintegration of transplanted people, overcoming the psychological, logistical and organizational barriers that have been hindering the practice.

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P-03

The ITA.LI.CA network: description and results of its activity

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Introduction: The incidence of hepatocellular carcinoma (HCC) is increasing in most Western countries, being one of the main causes of oncological mortality.

Aims: Description of a scientific network generated in order to assess the evolutionary scenario of HCC in Italy (epidemiology, clinical presentation, treatment and outcomes) and to provide evidence-based proposals to improve HCC management.

Materials and methods: The Italian Liver Cancer (ITA.LI.CA) is a scientific network created in 1989 to generate a database describing HCC patients. Demographic and clinical data of all consecutive patients were prospectively (retrospectively from 1987 to 1989) collected and updated every 2 years up to now. Data are collected in an on-line web site (www.progettoitalica.it) and, before statistical analysis, their consistency and accuracy are checked by a data-manager. Thereafter, the final version of the database becomes available (Excel format) for both ITA.LI.CA and external scientists to carry out the scientific projects approved by all ITA.LI.CA centers.

Results: ITA.LI.CA network currently includes 9573 patients (M/F = 7265/2307) managed in 27 Italian centers. Its scrutiny allowed researchers to publish 56 original articles and 8 letters on peer-reviewed journals regarding surveillance (18% of papers), tumour epidemiology (16%), staging (5%), prognosis (29%) and treatment (32%). The total *Impact Factor* of ITA.LI.CA articles is 671,2 (mean: 9,8). Two articles received the AISF award as the best Italian publication of the year in hepatology. The results of some articles had an innovative impact on guideline recommendations for HCC management, particularly in the field of *surveillance*, *cancer staging, transplant benefit* and *therapeutic hierarchy*.

Conclusions: ITA.LI.CA network is the largest permanent scientific grid of the Western world about HCC that has generated a huge source of data coming from clinical practice. The network analysis allowed researchers to produce original and innovative information, depicting the evolutionary scenario of HCC in our country, and improving recommendations for its management.

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P-04

Effect of alpha-fetoprotein on survival in HIV-infected patients with hepatocellular carcinoma

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Aim: The aim of the study was to investigate the association between alpha-fetoprotein (AFP) levels and HCC prognosis among people living with HIV (PLWH).

Materials and methods: We included PLWH from the CSLHIV cohort, with a HCC diagnosis between 1999–2018, cirrhosis, an AFP value available at HCC diagnosis. HCC staging and treatment allocation were based on BCLC system. HCC treatment was differentiated in curative (surgical resection, radiofrequency ablation and transplant) and non-curative (chemo or radioembolisation, systemic therapies, best supportive care).

Follow-up accrued from HCC diagnosis (BL) to the last clinical visit/loss to follow-up/death.

ROC curve analysis was applied to determine the optimal cut-off of BL AFP predicting death.

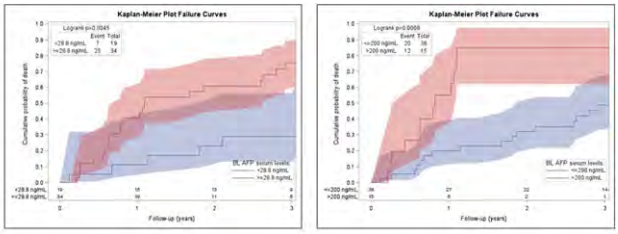
The Kaplan–Meier curves were calculated to estimate death probability. Factors associated with the risk of death were identified in two multivariate Cox proportional hazards models considering the 28.8 ng/mL or 200 ng/mL as cut offs for BL AFP.

Results: Fifty-three PLWH included: 85% male, median age 53 years (IQR = 48–56), median BL CD4+ was 392 cells/μL (IQR = 222–598), 81% with HIV-RNA <50 copies/mL; 34% in BCLC 0/A; 42% BCLC B/C; 24% BCLC D; 17% patients underwent transplant.

After a median follow-up of 20 months (IQR = 8–42), 32 (60.4%) PLWH died. The ROC curve analysis estimated the value of 28.8 ng/mL as optimal cut-off for the occurrence of death; BL AFP was ≥28.8 ng/mL in 63% pts, >200 ng/mL in 28%.

By 2-years, the cumulative probability of death was 23% (95%CI = 9.3%–50.4%) versus 61% (95%CI = 44.3%–77.8%) for BL AFP <28.8 and ≥28.8 ng/mL, 32.2% (95%CI = 19.2%–50.6%) versus 85% (95%CI = 62.2%–97.5%) for BL AFP ≤200 and >200 ng/mL (Figure 1).

At multivariable analysis: BL AFP resulted independently associated with increased risk of death after a diagnosis of HCC (Figure 2).



Time HCC	BL AFP <28.8 ng/mL	BL AFP ≥28.8 ng/mL	BL AFP ≤200 ng/mL	BL AFP >200 ng/mL
1 year	11.2% (2.9% - 37.9%)	40.6% (25.9% - 59.5%)	20.0% (10.0% - 37.4%)	55.0% (32.2% - 80.6%)
2 years	23.0% (9.3% - 50.4%)	60.9% (44.3% - 77.8%)	32.2% (19.2% - 50.6%)	85.0% (62.2% - 97.5%)

Figure 1. Cumulative probability of death according to BL AFP stratified according to the optimal cut-off 28.8 ng/ml or the 200 ng/ml.

	MODEL 1		MODEL 2	
	AHR* (95% CI)	P-value	AHR* (95% CI)	P-value
HCV				
Yes vs No	8.44 (1.25-57.0)	**0.029**	3.41 (0.54-21.61)	0.193
HBV				
Yes vs No	19.1 (2.39-152.0)	**0.005**	4.39 (0.81-23.94)	0.087
BCLC				
Intermediate/Advanced vs early stage	5.28 (0.49-56.4)	0.169	0.64 (0.12-3.54)	0.609
Terminal vs early stage	29.05 (1.92-439.2)	**0.015**	0.68 (0.10-4.67)	0.673
BL AFP (ng/mL)				
≥28.8 vs <28.8	37.98 (5.51-262.0)	**0.0002**	-	-
>200 vs ≤200	-	-	4.98 (1.59-15.59)	**0.006**
BL CD4+ cell count (cells/uL)				
Per 100-cells higher	0.84 (0.68-1.03)	0.094	0.93 (0.77-1.12)	0.460

* After adjusting for: HCC calendar year, age, gender, years of ART, number of nodules, HCC treatment strategy and BL HIV-RNA.

Figure 2. Multivariable analysis: factors associated with the risk of death after a diagnosis of HCC.

Discussion: Our analysis shows that, in PLWH, AFP levels higher than 28.8 at HCC diagnosis is an independent negative predictive marker for death.

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P-05

How does Trieste treat HCV in PWID? An effective coordination between addiction treatment service (SerD), the infective disease department and the liver clinic

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According to Italian data, people who inject drugs (PWID) have high prevalence of Hepatitis C Virus (HCV) infection (30-60%). PWID have inadequate access to directly acting antivirals (DAA) due to (1) their mistrust towards the healthcare system and (2) the lack of coordination between medical specialists who play a pivotal role in the diagnosis and treatment of HCV infection. We aim to describe the HCV -treatment cascade of care in Trieste on PWID.

Model description: Universal and free-of-charge infective screening is offered to PWID by SerD staff. Patients are introduced to counseling where HCV risk behaviors and harm reduction policies are carefully explained. HCV antibody detection represents the first-line of screening. Around 90% of HCV-antibody positive patients agree to further testing (i.e., HCV-RNA and genotype). Patients are further evaluated by abdominal ultrasound and liver elastography and then referred to: (1) the Infective Disease Department (adults and/or HIV-coinfected patients) or (2) the Liver Clinic (teenagers young adults, and/or patients with higher degree of liver fibrosis) – where the medical specialist prescribes DAA. Therapy administration and supervision are planned according to patients' compliance, socio-economic status, family support, and psychiatric comorbidities in order to avoid drop out and incorrect drug intake.

Effectiveness: Between January 2015 and December 2018, 255 individuals were treated for HCV infection, and 19 of those presented with HCV/HIV co-infection. 45 patients were referred to the liver clinic, whereas 210 to the infective disease department. The most prevalent genotype were 3 (51%, subtype 3a in 61%) and 1 (40%, subtype 1b in 57%). 177 patients (69%) presented fibrosis F0-2 at the beginning of therapy, 30 (12%) had F3, and 29 (11%) had F4. 249 (97.6%) patients had a sustained viral response at 12 weeks (SVR12), while 2 were non-responders, 2 had relapsing infection, and 2 presented with reinfection. According to the data, the SerD saw a drastic increase in supervised treatment of HCV positive individuals (compared to the total HCV treated patients in the Trieste Area): from 7% in 2015-16 to 36% in 2017 and 86% in 2018.

Conclusion: our HCV care model demonstrated how addiction treatment service (SerD) is fundamental in the delivery and supervision of HCV treatment in PWID. The goal of the system is to create a personalized and straightforward care process that appoints the complexity and vulnerability of the patient. Simplified, integrated, and more flexible plans that promote the therapeutic relationship between the patients and the SerD medical and nursing personnel, allow (1) quicker access to treatment (2) increased adherence to therapy, and (3) changes in risk behaviors, thus reducing reinfection rate and progressively decreasing virus prevalence in the target population.

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P-06

Resources optimization in DAA-based HCV treatment through a simplified on-treatment schedule

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Introduction: From May 2017, AIFA has allowed to treat low-fibrotic HCVRNA(+)pts with DAA. In order to maintain an unmodified access to cure, a different and simplified treatment scheduled had to be implemented.

Aim: We aimed to evaluate both the outcome and the cost-efficacy of the DAA-therapy with the short schedule.

Materials and methods: the data of 302 patients treated with DAA since Jan-2018 to Jan-2019 have been prospectively analyzed. Twenty patients (Liver transplant recipients/waitlisted for liver transplant/CHILD B) were followed with long schedule: T0 (beginning of DAA therapy) and at T4-T8-T12weeks of therapy and at 4–12 weeks post-treatment). 275 patients were treated adopting the simplified schedule: visit only at T0 and at post treatment 12weeks; the monthly DAA prescriptions, and the required biochemical testing were performed adopting a back-office modality. A dedicated form was provided for each patient to facilitate the communication with the Centre.

Results: the outcome of the DAA treatment of 302 patients was analyzed. over one year, 275/302 were treated with short schedule. Baseline data of the short-schedule group are reported in Table

1. Only 2/275 patients have formally requested for a on-treatment medical consultation, and 35/275 requested a brief interview with either a physician or a nurse. No statistically significant differences were observed between patient that had requested an interview or additional visit (group 1), and patients who did not (group 2). The SVR rate was 97.9% (97.5% in group 2). With the Simplified on-treatment schedule we avoided 1012 visits, 253 working-hours for the physician and the loss of 3,68 working-days for patient.

Conclusions: The adoption of the short schedule during the DAA-therapy allowed unmodified high SVR12 rates (97.5%) with the advantage of avoiding unnecessary visits, saving time and money (that we can use to treat more patients) and working days of the patient with further saving for the society.

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P-07

Current epidemiology of HCV in Sicily: the RESIST-HCV model

V. Di Marco [1,3], F. Cartabellotta [3], W. Mazzucco [2], V. Calvaruso [1], S. Petta [1], S. Mazzola [2], R. Cusimano [2], R. Amodio [2], G. Scifo [3], M. Russello [3], B. Cacopardo [3], G. Squadrito [3], G. Raimondo [3], T. Pollicino [4], F. Ceccherini-Silbertein [4], F. Vitale [2], C. Cammà [1], A. Craxì [1,3], on behalf of RESIST-HCV

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Background: Real-world data to guide hepatitis C virus (HCV)-related public health initiatives and linkage to care of patients are lacking in our region.

Aims: To describe the epidemiological features of a large cohort of patients with chronic HCV infection from Sicily included in a regional network aimed at DAA treatment (RESIST-HCV).

Methods: Demographic and clinical data were recorded on a web-based platform before starting treatment with DAAs. Gender, year of birth, HCV genotype, co-infections, stages of liver disease and co-morbidities were analyzed. Chi-square with Yates correction was appliedto assess the differences between cohorts.

Results: Overall, 15,270 patients were registered on the HCV-RESIST platform from March 2015 to March 2019. The analysis of demographic and viral features showed a clear-cut bimodal distribution, defining two cohorts of patients. The first (cohort 1) includes 9.939 patients (65%) born between the years 1930 and 1959, while the second (cohort 2) included 5.331 patients (35%) born between 1960 and 1999. When comparing the two cohorts, cohort 1 had a higher rate of infection with HCV Gt 1b or 2 (90% vs 47%; $p < 0.0001$), higher rate of cirrhosis (49.5% vs 37.5% in cohort 2; $p < 0.001$), hepatocellular carcinoma (3.3% vs 0.6%; $p < 0.0001$), diabetes (26.8% vs 10.3%; $p < 0.0001$) and of arterial hypertension (50.4% vs 13.5%; $p < 0.0001$). By converse, in cohort 2 there was a higher proportion of males (71.3% vs 48.7%; $p < 0.0001$), subjects naïve to IFN-based treatment (66.2% vs 62.5%; $p < 0.0001$), infection with HCV Gt 1a, 3 or 4 (53% vs 10%; $p < 0.0001$), HIV co-infection (7.8% vs 1%; $p < 0.0001$), and PWIDs(12% vs 1%; $p < 0.0001$).

Conclusions: In Sicily, a region where HCV is still endemic, chronic HCV infection has a bimodal distribution, with two different cohorts affected. One cohort reflects a first epidemic wave, mostly fueled by Gt 1b and 2, through unsafe medical practices and non-sexual intrafamilial spreading between 1940 and 1990. About half of these patients has developed cirrhosis and many have co-morbidities that may worsen the prognosis. Another cohort originated between 1970 and 2000 mostly through needle sharing and unsafe sex, thus frequently associating with HIV, and is sustained mostly by Gt1a and 3. In order to reach the WHO elimination targets by 2020, graduated screening policies according to this mode of distribution of HCV should be devised.

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P-08

Second-generation DAAs for HCV: real-life efficacy in the RESIST-HCV cohort

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Background and aims: RESIST-HCV (Rete Sicilia Selezione Terapia – HCV) registers all patients in Sicily with chronic HCV infection treated with DAAs, allowing a real-time measure of their efficacy in practice. This analysis aims to evaluate second-generation regimens (Sofosbuvir plus Velpatasvir: SOF/VEL; Glecaprevir plus Pibrentasvir: GLE/PIB;Elbasvir/Grazoprevir: EBV/GRZ), in order to evaluate SVR rates of DAA-naïve patients to currently available regimens.

Methods: We analyzed 4,087 patients who received treatment between March 2017 and December 2018 whose SVR12 data were available in the RESIST-HCV database by June 2019. Cirrhosis was diagnosed by liver stiffness ^{3}12 KPa (Fibroscan) and/or by presence of esophageal varices at endoscopy and/or by a liver biopsy with METAVIR stage 4 fibrosis.

Results: By ITT analysis 95.1% of patients (3,878/4,078) achieved SVR. Overall, 125 patients (3.1%) did not complete the assigned therapy. Of them, 11 patients (0.3%) died for liver-related (5 patients) or unrelated (6 patients) causes while on treatment. Twenty patients (0.5%) discontinued treatment due to adverse events and 94 patients (2.2%) did not have virology available at end of therapy (ETR) or for SVR evaluation. Seventy-five patients (1.8%) did not achieve SVR: of them, 14 were still HCV-RNA positive at the end of therapy and 61 showed a virological relapse after ETR. By PP analysis 98.1% of patients (3878/3953) obtained an SVR. The rates of PP SVR according to HCV genotype (Gt) and stage of disease are reported Table 1. Patients with chronic hepatitis and Gt 1a, 1b, 2 or 4 obtained SVR rates higher than 99% when treated with pangenotypic regimes (SOF/VEL or GLE/PIB). SVR rates above 96% were obtained in patients with cirrhosis and Gt 1a, 1b, 2 or 4 treated with SOF/VEL or GLE/PIB. Adding ribavirin to SOF /

VEL in genotype 3 patients with chronic hepatitis or cirrhosis did not enhance the rate of SVR. Genotype 1b patients with chronic hepatitis or cirrhosis, when treated with EBV/GRZ had an SVR in 95.9% and 94.7% of cases, respectively, mostly due to post-ETR relapses.

Conclusions: Current DAA regimens, especially if pangenotypic, obtain response rates of at least 95% in a real-life situation. Adding ribavirin to SOF/VEL seems unnecessary in Gt3 patients, regardless of fibrosis.

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P-09

Screening and linkage to care of prisoners with HCV infection: the RESIST-HCV project

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Background: In prisons there are high prevalence of hepatitis C virus (HCV) infection, high rate of PWID and a substantial risk of HCV transmission. Epidemiological studies are needed to evaluate the rate of prisoners with chronic HCV hepatitis and to establish how many of them need Direct Acting Antiviral (DAA) therapy.

Methods: We conducted a cross-sectional study to explore the prevalence of HCV infection in all prisoners of Pagliarelli-Lorusso prison in Palermo (Sicily). At July 2019 prisoners received information on the virological test, the diagnosis of chronic hepatitis and the possibility of obtaining antiviral therapy inside the prison. Anti-HCV antibodies was detected by OraQuick HCV rapid oral test. Prisoners with positive screening performed serum HCV-RNA and viral genotype, evaluated liver disease stage by Fibroscan and received antiviral therapy. All prisoners signed an informed consent to use demographic, clinical and virological data. Chi-square test was used to analyze differences between groups.

Result: Among 1,142 prisoners (87.0% of entire population of the prison) who participated in the study, 1,080 (94.5%) accepted to perform oral test for HCV antibodies. Prisoner had a mean age of 42 ± 13 years without differences in 1,006 males (93.1%) and 74 females (6.9%). Overall, 50 prisoners (4.6%) resulted HCV antibody-positive: 43 out of 1,006 males (4.3%) and 7 out of 74 females (9.5%) ($p = 0.07$). Twenty-four out of 96 intravenous drug user (IVDU) prisoners (25%) and 26 out of 984 no-IVDU prisoners (2.6%) were anti-HCV positive ($p < 0.0001$). The prevalence of HCV antibody-positive was 22.3% (19/85) among IVDU males and 45.5% (5/11) among IVDU females ($p = 0.16$). Sixteen out of 24 IVDUs (66.6%), but only 10 out of 26 prisoners (38%) no-IVDUs had received a previous diagnosis of HCV infection ($p = 0.05$). Eleven out of 26 prisoners (42.3%) who knew they had an HCV infection (5 of 24 IVDUs and 6 of 26 no-IVDUs) had already received a cycle of antiviral therapy.

Conclusions: The prevalence of HCV infection among prisoners is at least 4 times greater than in the general population and the main risk factor is a history of injecting drug use. The majority of infected IVDUs know they have HCV infection, while only one third of infected no-IVDU people were aware of having HCV infection. Only 40% of people infected with HCV had received antiviral therapy. In prisons it is necessary on side test and treat project to eliminate the infection and linkage to care patients with chronic liver disease.

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P-10

MetaLiverCat: the NAFLD/NASH multidisciplinary board at Fondazione Policlinico Gemelli IRCCS

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Introduction: The development of patient journey for patients with Nonalcoholic fatty liver disease (NAFLD) and non-alcoholic steatohepatitis (NASH) is a current challenge for outpatient liver centers. The early identification of high-risk patients with NAFLD/NASH require multidisciplinary approach in order to assure the appropriate specialistic referral in a personalized model of chronic care program.

Aim: We have recently created an intra-hospital network for referring patients to multidisciplinary evaluation aimed at improving the detection of cases of high-risk NAFLD/NASH phenotype.

Materials and method results: In October 2018 we started a NAFLD/NASH multidisciplinary board named 'Metabolic Liver Disease at Catholic University' (MetaLiverCat). MetaLiverCat is composed by a team of hepatologists, diabetologists cardiologists, bariatric surgeons, nutritionists, radiologists, pathologists and endocrinologists. The board meets periodically and patients' referral from all the Units of the entire hospital is performed by an electronical sheet recording clinical, histological and radiological data. In a pilot period we recorded that NAFLD/NASH patients referred were mainly male (59.5%), mean age 55 ± 13 y, BMI 33.0 ± 9.1 kg/m^2. Overall, the most prevalent comorbidity was arterial hypertension (64.3%), 54.8% had metabolic syndrome and 40.2% were type 2 diabetics. The main reason of referral was for evaluating the indication to liver biopsy for subjects within the grey area of

non-invasive tests for fibrosis (42.9%). The medical treatment was reviewed in 38.1% of subjects and in 14.3% bariatric evaluation was indicated. In 21.4% of subjects the MetaLiverCat agreed for new trial screening.

Conclusions: The multidisciplinary approach for NAFLD/NASH patients is important for early identification of high-risk subjects and it is able to assure the more appropriate medical decision. The MetaLiverCat seems to be able to collect cases from different medical specialties and the team is able to improve the awareness. The advantage for the patient lies in the possibility of having a shared medical approach between medical specialists of different branches for a personalized approach.

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